MSCT

Masterclass in

Systemic Cancer Therapy featuring

personalised medicine in cancer therapeutics – past, present, future

Malaysian Oncological Society

UNIVERSITY OF MALAYA

Date : 15th – 16th March 2019
Venue : TJ Danaraj Auditorium, Universiti Malaya, Faculty of Medicine
Email : register.msct2019@gmail.com (For Registration)
enquiry.msct2019@gmail.com (For Enquiry)

(CME points will be awarded)

TECENTRIQ® IS THE FIRST AND ONLY APPROVED ANTI-PDL1 CANCER IMMUNOTHERAPY

THE STRENGTH OF SURVIVAL

OAK: The Largest Phase III Cancer Immunotherapy Study in Previously Treated Advanced NSCLC, Regardless of PD-L1 Expression[1,2]

TECENTRIQ		Docetaxel
13.8 months median OS (95% CI, 11.8, 15.7)	VS	**9.6** months median OS (95% CI, 8.6, 11.2)

HR=0.73 (95% CI, 0.62, 0.87); P=0.0003

- 55% of patients were alive at 1 year with TECENTRIQ vs 41% with docetaxel
- Superior median OS vs docetaxel in both non-squamous (15.6 vs 11.2 months; HR=0.73; 95% CI, 0.60, 0.89) and squamous (8.9 vs 7.7 months; HR=0.73; 95% CI, 0.54, 0.98) NSCLC
- Superior survival at all levels of PD-L1, including for patients with little or no expression (TC and IC < 1%: 12.6 vs 8.9 months; HR=0.75)

References: 1. TECENTRIQ Product Insert, Malaysia, Dec 2018. **2.** Rittmeyer A, Barlesi F, Waterkamp D, et al; OAK Study Group. Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. Lancet. 2017;389:255-265.

Basic Succinct Statement
Trade Name: Tecentriq® **Active Ingredient**: Atezolizumab
Therapeutic Indications: Tecentriq is indicated for the treatment of patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on approved therapy for these aberrations prior to receiving Tecentriq. **Dosage and Administration**: Tecentriq must be administered as an intravenous (IV) infusion under the supervision of a qualified healthcare professional. Do not administer as an IV push or bolus. Substitution by any other biological medicinal product requires the consent of the prescribing physician.The recommended dose is 1200 mg administered by IV infusion every three weeks. The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated, all subsequent infusions may be administered over 30 minutes. **Contraindications**: Tecentriq is contraindicated in patients with a known hypersensitivity to atezolizumab or any of the excipients. **Warnings and Precautions**: In order to improve the traceability of biological medicinal products, the trade name and the batch number of the administered product should be clearly recorded (or stated) in the patient file. Monitor for Immune Related Adverse Reactions (pneumonitis, hepatitis, colitis, endocrinopathies, meningoencephalitis, neuropathies, pancreatitis, myocarditis) **Undesirable effects**: Diarrhea, Nausea, Vomiting, Fatigue, Asthenia, Pyrexia, Decreased appetite, Arthralgia, Dyspnea, Rash, Pruritus **Pregnancy and Lactation**: Tecentriq is not recommended during pregnancy unless the potential benefit for the mother outweighs the potential risk to the fetus. As the potential for harm to the nursing infant is unknown during breast feeding, a decision must be made to either discontinue breast-feeding or discontinue Tecentriq therapy. **Packaging**: Single-use vial containing 20 ml preservative-free, colorless to slightly yellow solution, at a concentration of 60 mg/ml. Each vial contains a total of 1200 mg Atezolizumab. Full details on composition, indications, contraindications, side effects, dosage and precautions are available upon request (MYTecentriq0119CDS5.0).

Adverse Event Reporting:
Roche is committed to the collection and management of safety information relating to our products and we highly encourage healthcare professionals to report adverse events, outside of clinical trial, if any, to our Roche Drug Safety team at my.drugsafety@roche.com or call +603-7628 5600 or fax to +603-7628 5605.

For Healthcare Professionals Only

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TEC230418MYa

TECENTRIQ™
atezolizumab

MESSAGE
FROM HEAD OF DEPARTMENT

Dr Rozita Abdul Malik

Clinical Oncology Unversity of Malaya Medical Centre

I would like to personally welcome each of you to the Masterclass in Systemic Cancer Therapy (MSCT) 2019. This is the third time the Clinical Oncology Unit, Faculty of Medicine, UM in collaboration with Malaysia Oncological Society (MOS) is conducting a comprehensive course on the pharmacology of systemic cancer therapy. MSCT 2019 is enriched further with a selection of new topics and special feature on personalized medicine in cancer therapeutics. The program was designed to include various aspect of systemic cancer therapy including special situations related to it. This course may serve as a platform for all of you to share knowledge and experience in managing patient with cancer using systemic therapy. We hope that you will gain as much knowledge as possible and enjoy the course. Thank you for attending.

Organizing Committee

1. Nur Fadhlina Abdul Satar (Chairperson)
2. Adlinda Alip
3. Andrea Lo Hui Sang
4. Arylne Low Su Sien
5. Belinda Ng Yee Ping
6. Carolyn Eng Chai Hui
7. Chan Renn Syin
8. Christpine Menti Sarie
9. Hashalatha Ganesan
10. Mariam Zafirah Bt Mustazah
11. Nelson Wong
12. Nur Faizah Bt Ab Muin
13. Ooi Po Lin
14. Rozita Abdul Malik
15. Toh Yok Yong
16. Verra Ng Ru Hui
17. Wan Zamaniah Wan Ishak
18. Yusra Bt Hadi
19. Nelson Wong Peng Wai

Scientific Committee

1. Adlinda Alip
2. Anita Zarina Bustam
3. Ho Gwo Fuang
4. Jasmin Loh Pei Yuin
5. Marniza Saad
6. Nur Fadhlina Abdul Satar
7. Rozita Abdul Malik
8. Wan Zamaniah Wan Ishak

Faculty List

1. Ang Soo Fan
2. Anushya A/P Vijayanathan
3. Bee Ping Chong
4. Carolyn Eng Chai Hui
5. Fuad Ismail
6. Henning Loo Cheng Kien
7. Ho Kean Fatt
8. Ibtisam Muhamad Nor
9. Junie Khoo Yu Yen
10. Khairiyah Sidek
11. Lim Yong Yan
12. Loong Ly Sia
13. Malwinder Singh Sandhu
14. Marfuah Nik Eezamuddeen
15. Mastura Md Yusof
16. Mukhri Hamdan
17. Muthukkumaran Thiagarajan
18. Nahjatul Abdul Ghafar
19. Nur Fadhlina Abdul Satar
20. Soo Hoo Hwoei Fen
21. Tan Ai Lian
22. Tan Chih Kiang
23. Tan Wen Chieh
24. Vaishnavi Jeyasingam
25. Vincent Phua Chee Ee
26. Wan Zamaniah Wan Ishak
27. Wong Yoke Fui
28. Yusmanatul Airah Bt Yusof

DECADES
of improving the quality of life for cancer patients

For healthcare professionals only.

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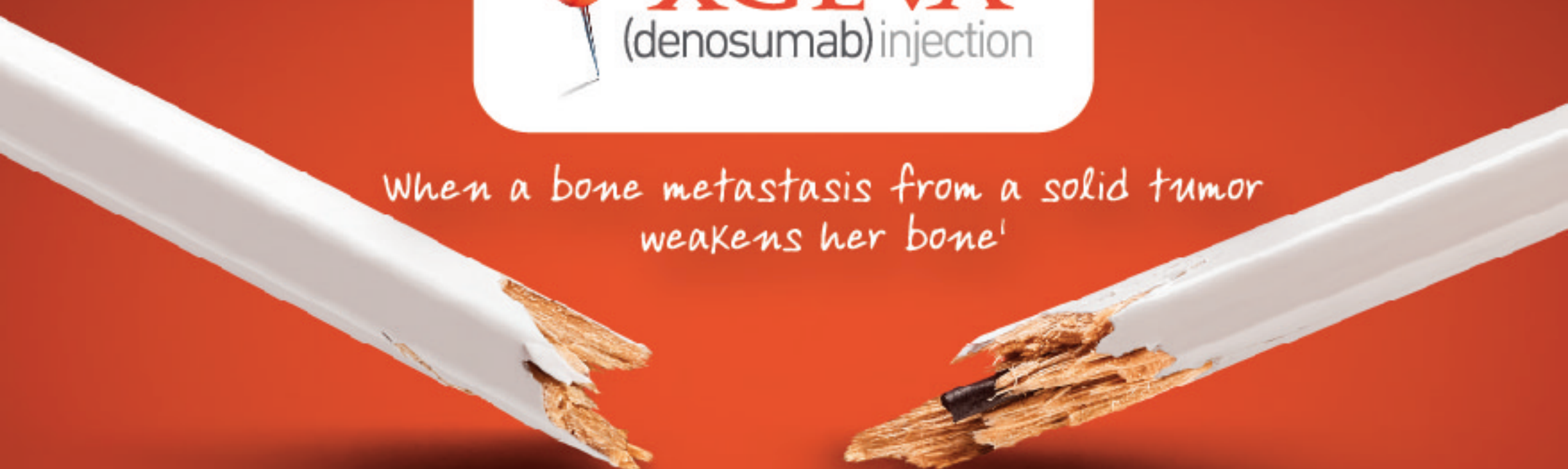
Oncology

XGEVA® (denosumab) injection



PREVENTING BONE COMPLICATIONS* HELPS KEEP WHAT MATTERS INTACT

*Bone complications, also known as skeletal-related events (SREs), are defined as radiation to bone, pathologic fracture, surgery to bone, and spinal cord compression.[2]

XGEVA® is indicated for prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours.[3]

Please review full product information before prescribing

XGEVA® ABBREVIATED PRODUCT INFORMATION

INDICATIONS: Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumours; **CONTRAINDICATIONS:** Hypersensitivity to denosumab or any components of XGEVA; severe untreated hypocalcaemia; unhealed lesions from dental or oral surgery. **PRECAUTIONS:** Supplementation with calcium and vitamin D is required in all patients unless hypercalcaemia is present. Correct hypocalcaemia prior to initiating therapy. Monitor calcium levels at baseline and throughout the duration of treatment especially within the first few weeks, and if symptoms of hypocalcaemia occur. Additional supplementation with calcium if hypocalcaemia occurs. Available data do not support use of XGEVA in multiple myeloma. Caution in patients with known risk factors for osteonecrosis of the jaw (ONJ); oral and dental exam prior to therapy recommended; maintain good oral hygiene during treatment. Avoid invasive dental procedures where possible. Hypercalcaemia has been observed weeks to months following treatment discontinuation in patients with growing skeletons. Reports of a typical femoral fracture. **PREGNANCY:** XGEVA is not recommended for use in pregnant women and breast-feeding. Safety and efficacy in paediatrics not established. **ADVERSE EFFECTS:** Hypocalcaemia, hypophosphataemia, dyspnoea, ONJ. **DOSAGE & ADMINISTRATION:** Single subcutaneous injection of 120 mg once every 4 weeks. Supplement with calcium and vitamin D unless hypercalcaemia present. No dose adjustment required in the elderly or in renal impairment.

AMGEN internal reference: 140716MY_Xgeva

References: 1. American Cancer Society. Bone metastasis. American Cancer Society Web site. https://www.cancer.org/treatment/understanding-your-diagnosis/advanced-cancer/finding-bone-metastases.html. Revised December 15, 2016. Accessed January 10, 2018. **2.** Gralow JR, Biermann JS, Farooki A, et al. NCCN Task Force report: bone health in cancer care. J Natl Compr Canc Netw. 2013;11(suppl 3):s1-s50. **3.** XGEVA® Malaysia Prescribing Information.

For Medical/Healthcare Professionals Only

Before prescribing, please refer to the full prescribing information, which is available upon request.
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Masterclass in Systemic Cancer Therapy (MSCT) 2019

By Department of Clinical Oncology, University of Malaya Medical Centre, Universiti Malaya (UM)
In collaboration with Malaysian Oncological Society (MOS)

Date : 15 - 16th March 2019
Venue : TJ Danaraj Auditorium, Faculty of Medicine, UM

MSCT 2019 is the third event following the successful inaugural event last year. The agenda for MSCT 2019 is enriched further with a selection of new topics and special feature on personalized medicine in cancer therapeutics.

Target Audience

1) Trainees and medical officers in oncology
2) Doctors in other specialties involved in management of patients with cancer
3) Oncologists wishing to get a refresher course
4) Oncology nurses
5) Pharmacists

Objectives

- Understand the history of chemotherapy
- Understand the principles of pharmacokinetics and pharmacodynamics
- Understand the principles of drug development and phase I, II, II trials
- Understand the principles of conventional cytotoxic chemotherapy and differentiate it with targeted agents and immune-oncologic therapy
- Understand the mechanism of action, clinical uses and side effects of individual cytotoxic, hormone and biologic agent
- Understand the principles of anticancer drug resistance and strategies to overcome it
- Understand the tumor response assessment, the different survival markers as measures of evaluating the effectiveness of the drugs
- Advances in cancer drug delivery development – nanotechnology, liposomal, biosimilar etc
- Understand the mechanism of action, clinical uses and side effects of supportive therapy

Course Synopsis

The emphasis is on:

1) Principles of pharmacokinetics and pharmacodynamics in relation to drug dosing, scheduling and modifications
2) Role of clinical trials in the development of new anti-cancer agents
3) The use of cytotoxic drugs, hormones and biological therapies in clinical practice, their modes of action, side-effects, drug interaction and resistance
4) Preventive measures, monitoring and management of toxicities of anticancer agents
5) Pharmacological agents used in the supportive care of patients with cancer: indication, mode of action and side-effects

RAMUCIRUMAB + PACLITAXEL

THE FIRST AND ONLY FDA-APPROVED combination regimen included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with a CATEGORY 1 recommendation

for the treatment of locally advanced or metastatic gastric or GEJ adenocarcinoma in the second-line setting[1,2,3]

A PREFERRED OPTION[1,2]

CATEGORY 1 NCCN Guidelines® Recommendations:

Locally Advanced or Metastatic Gastric Adenocarcinoma*[2]

- ✓ Single-agent ramucirumab
- ✓ Ramucirumab with paclitaxel

Locally Advanced or Metastatic Esophagogastric Junction Adenocarcinoma†[3]

- ✓ Single-agent ramucirumab
- ✓ Ramucirumab with paclitaxel

CATEGORY 1: Based upon high-level evidence, there is uniform National Comprehensive Cancer Network® (NCCN®) consensus that the intervention is appropriate.

Abbreviated Package Insert:

AI: ramucirumab. **I:** Gastric cancer: Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. Colorectal cancer: Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. Non-small cell lung cancer (NSCLC): Cyramza in combination with docetaxel is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy. **D:** Gastric cancer and gastro-oesophageal junction (GEJ) adenocarcinoma: Cyramza in combination with paclitaxel: 8 mg/kg on Days 1 and 15 of a 28-day cycle, prior to paclitaxel infusion. Cyramza as a single agent: 8 mg/kg every 2 weeks. Colorectal cancer: 8 mg/kg every 2 weeks administered by intravenous infusion, prior to FOLFIRI administration. NSCLC: 10 mg/kg on Day 1 of a 21-day cycle, prior to docetaxel infusion. **CI:** Hypersensitivity to the active substance or to any of the excipients. **SP:** Arterial thromboembolic events, gastrointestinal perforations, severe bleeding, pulmonary haemorrhage in NSCLC, gastrointestinal haemorrhage, infusion-related reactions, hypertension, impaired wound healing, hepatic impairment, fistula, proteinuria, stomatitis, renal impairment, patients on sodium restricted diet, elderly patients with NSCLC **AR:** Most common: neutropenia, fatigue/asthenia, leukopenia, diarrhoea, epistaxis, and stomatitis. **Presentations:** 100mg/10ml or 500mg/50ml vial.

References: 1. CYRAMZA (ramucirumab) package insert Malaysia March 2017. **2.** Referenced with permission from The NCCN Clinical Practice Guidelines n Oncology (NCCN Guidelines®) for Gastric Cancer V.3.2015. © National Comprehensive Cancer Network, Inc. 2015. All rights reserved. Accessed February 1, 2016. To view the most recent and complete version of the guidelines, go online to http://www.nccn.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN content are trademarks owned by the National Comprehensive Cancer Network, Inc. **3.** Referenced with permission from The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Esophageal and Esophagogastric Junction Cancers V.3.2015. © National Comprehensive Cancer Network, Inc. 2015. All rights reserved. Accessed February 1, 2016. To view the most recent and complete version of the guidelines, go online to http://www.nccn.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN content are trademarks owned by the National Comprehensive Cancer Network, Inc.

* NCCN Guidelines for Gastric Cancer V.3.2015 recommend single-agent ramucirumab (CYRAMZA) and ramucirumab (CYRAMZA) in combination with paclitaxel as preferred second-line treatment options for locally advanced or metastatic gastric adenocarcinoma.

† NCCN Guidelines for Esophageal and Esophagogastric Junction (EGJ) Cancers V.3.2015 recommend single-agent ramucirumab (CYRAMZA) and ramucirumab (CYRAMZA) in combination with paclitaxel as preferred second-line treatment options for locally advanced or metastatic EGJ adenocarcinoma.

CYRAMZA® (ramucirumab)

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for 18 cycles in patients with HER2+ eBC at high risk of recurrence[1]

THE GOAL IS CURE. FURTHER REDUCE HER RISK

WITH THE PERJETA-HERCEPTIN ADVANTAGE.

The PERJETA-Herceptin combination plus chemotherapy further reduces the risk of recurrence by almost 25% for patients at high risk of recurrence in the curative setting[2]

Indications for early breast cancer (eBC)[1]:

Perjeta is indicated in combination with Herceptin and chemotherapy for the:

- neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either >2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer
- adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence

PERJETA Herceptin® trastuzumab

DUAL HER2 BLOCKADE. PROVEN SYNERGY.

HER2=human epidermal growth factor receptor 2.

Basic Succinct Statement

Trade Name: Perjeta® **Active Ingredient:** Pertuzumab **Therapeutic Indications:** i) Metastatic Breast Cancer: Perjeta is indicated in combination with Herceptin and docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. ii) Early Breast Cancer: Perjeta is indicated in combination with Herceptin and chemotherapy for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either >2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer, and adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.**Dosage and Administration:** Initial dose of 840 mg administered as 60 minutes iv infusion, followed every 3 weeks thereafter by 420 mg administered as an IV infusion over 30 to 60 minutes. i) Metastatic Breast Cancer: Perjeta should be administered in combination with Herceptin and docetaxel until disease progression or unmanageable toxicity. ii) Early Breast Cancer (EBC): In the neoadjuvant setting (before surgery), it is recommended that patients are treated with Perjeta for 3-6 cycles depending on the regimen chosen in combination with Herceptin and chemotherapy. In the adjuvant setting (after surgery), Perjeta should be administered in combination with Herceptin for a total of 1 year (maximum 18 cycles or until disease recurrence, or unmanageable toxicity, whichever occurs first), as part of a complete regimen for early breast cancer, including standard anthracycline and/ or taxane-based chemotherapy. Perjeta and Herceptin should start on Day 1 of the first taxane-containing cycle and should continue even if chemotherapy is discontinued. Patients who start Perjeta and Herceptin in the neoadjuvant setting should continue to receive adjuvant Perjeta and Herceptin to complete 1 year of treatment. **Contraindications:** Known hypersensitivity to pertuzumab or to any of its excipients. **Warnings and Precautions:** Left ventricular dysfunction, infusion-related reactions and hypersensitivity reactions / anaphylaxis.**Undesirable effects:** The most common adverse drug reactions (ADRs) (>30%) from the pooled trial data with Perjeta were diarrhoea, alopecia, nausea, fatigue, neutropenia and febrile neutropenia. **Pregnancy and Lactation:** Should be avoided during pregnancy unless the potential benefit for the mother outweighs the potential risk to the foetus. For lactation, the potential for absorption and harm to the infant is unknown. **Packaging:** Vials 420 mg / 14 ml. Full details on composition, indications, contraindications, side effects, dosage and precautions are available upon request (MYPerjeta0618/CDS9.0).

Basic Succinct Statement

Trade Name: Herceptin® **Active Ingredient:** Trastuzumab **Therapeutic Indications:** i) HER2 positive Metastatic Breast Cancer (MBC): as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease; in combination with paclitaxel or docetaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease;dombination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC. ii) HER2 positive Early Breast Cancer (EBC): following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable); following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel; in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin; in combination with neoadjuvant chemotherapy followed by adjuvant Herceptin for locally advanced (including inflammatory) breast cancer or tumours >2cm in diameter. iii) HER2 positive Metastatic Gastric Cancer (MGC): first-line treatment for HER2 positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction, in combination with capecitabine or 5-FU and cisplatin. **Dosage and Administration:** MBC & EBC Weekly: Loading dose of 4 mg/kg, subsequent doses of 2 mg/kg; MBC, EBC and MGC 3-weekly: loading dose of 8 mg/kg, subsequent doses of 6 mg/kg. Contraindications: Known hypersensitivity to trastuzumab or to any other component of the product. **Warnings and Precautions:** Cardiomyopathy, infusion/administration-related reactions (IRRs), pulmonary reactions, cardiac dysfunction. **Undesirable effects:** IRRs/ARRs/hypersensitivity, cardiac dysfunction, haematological toxicity, hepatic and renal toxicity, diarrhoea, infection. **Pregnancy and Lactation:** Should be avoided during pregnancy and lactation. **Packaging:** 150mg single dose vial or 440mg multidose vial. Full details on composition, indications, contraindications, side effects, dosage and precautions are available upon request (MYHerceptin0518/CDS18.0).

PERJETA-Herceptin in pregnancy

- If a patient becomes pregnant while receiving PERJETA and Herceptin, or within 7 months following the last dose of PERJETA and Herceptin, please immediately report pregnancy to the local Roche Adverse Event Line at (Tel) +603-78285800 or through email at my.drugsafety@roche.com.
- Additional information will be requested during a PERJETA and Herceptin-exposed pregnancy and the first year of the infant's life. This will enable Roche to better understand the safety of PERJETA and Herceptin and to provide appropriate information to health authorities, healthcare providers, and patients.
- For additional information, please refer to PERJETA and Herceptin approved pack insert.

References:

1. PerjetaPack Insert MYPerjeta0618CDS9.0 **2.** von Minckwitz G, Procter M, de Azambuja E, et al. Adjuvant Pertuzumab and Trastuzumab in Early HER2-Positive Breast Cancer. N Engl J Med, 2017;377(2):122–131.

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PM-MY-0173-02-2019

AGENDA

Day 1 : 15th March 2019 Friday

Introductory Session

07:30 - 08:15	**Registration**	
08:15 - 08:25	**Welcome address**	**Assoc. Prof. Dr. Rozita Abdul Malik** HOD, Dept. of Clinical Oncology, UMMC

Plenary 1

Chairperson : **Prof Wan Zamaniah**

08:25 - 08:45	**Drug development: From discovery to clinical application**	**Prof. Dato' Dr. Fuad Ismail** Clinical Oncologist, UKM Medical Centre
08:45 - 09:05	**The pharmacological aspect of cytotoxics** Supported by Fresenius Kabi	**Prof. Dato' Dr. Fuad Ismail** Clinical Oncologist, UKM Medical Centre
09:05 - 09:25	**Response assessment of systemic cancer therapy** Supported by Abbvie	**Dr. Marfu'ah Nik Eezamuddeen** Clinical Oncologist, Universiti Teknologi MARA
09:25 - 09:45	**Acute and late toxicity of systemic treatment**	**Dr. Muthukkumaran Thiagarajan** Clinical Oncologist, Hospital Kuala Lumpur
09:45 - 10:05	**Alkylating agents**	**Dr. Tan Wen Chieh** Pharmacist, Universiti Malaya Medical Centre
10:05 - 10:35	**Platinum agents** Supported by Sanofi	**Loong Ly Sia** Pharmacist, UKM Medical Centre
10:35 - 10:45	**Q&A**	**All Speakers**

Plenary 2

Chairperson : **Prof Rozita Abdul Malik**

10:45 - 11:05	**Antimetabolites** Supported by Eli Lilly	**Dr. Khairiyah Sidek** Clinical Oncologist, Universiti Teknologi MARA
11:05 - 11:25	**Antimicrotubules** Supported by Eisai	**Carolyn Eng Chai Hui** Pharmacist, Universiti Malaya Medical Centre
11:25 - 11:45	**Topoisomerase inhibitors**	**Lim Yong Yan** Pharmacist, Universiti Malaya Medical Centre
11:45 - 12:05	**Managing nausea and vomiting** Supported by MSD	**Assoc. Prof. Dr. Wan Zamaniah Wan Ishak and Wan Mohammad** Clinical Oncologist, Universiti Malaya Medical Centre
12:05 - 12:25	**Mechanism of drug resistance**	**Dr. Wong Yoke Fui** Clinical Oncologist, Institut Kanser Negara
12:25 - 12:35	**Q&A**	**All Speakers**
12:35 - 13:05	**FEATURE TALK: Personalized medicine in cancer therapeutics - Past, present and future** Tea symposium supported by Merck Serono	**Dr. Ho Kean Fatt** Clinical Oncologist, Mt Miriam Cancer Hospital
13:05 - 14:30	**BREAK**	

Plenary 3

Chairperson : **Prof Wan Zamaniah**

14:30 - 15:00	**Analgesics for cancer pain** Supported by Mundipharma	**Dr. Vaishnavi Jeyasingam** Clinical Oncologist, Hospital Kuala Lumpur
15:00 - 15:30	**Tailoring treatment in special situations**	**Dr. Nahjatul Abdul Ghafar** Clinical Oncologist, Hospital KK Sabah
15:30 - 16:00	**Chemotherapy and pregnancy**	**Dr. Mastura Md Yusof** Clinical Oncologist, Pantai Hospital Kuala Lumpur
16:00 - 16:30	**Biomarkers & relevance to clinical practice**	**Dr. Mastura Md Yusof** Clinical Oncologist, Pantai Hospital Kuala Lumpur
16:30 - 16:40	**Q&A**	**All Speakers**
16:40 - 17:00	**Quiz (Plenaries 1-3)**	
17:00 - 17:10	**CLOSING Day 1**	

AGENDA

Day 2 : 16th March 2019 Saturday

Plenary 4

Chairperson : **Dr Adlinda Alip**

08:15 - 08:45	**VEGF-targeted therapy** Supported by Roche	**Assoc. Prof. Dr. Wan Zamaniah Wan Ishak and Wan Mohammad** Clinical Oncologist, Universiti Malaya Medical Centre
08:45 - 09:15	**EGFR-targeted therapy** Supported by Boehringer Ingelheim	**Dr. Junie Khoo Yu Yen** Clinical Oncologist, Hospital Umum Sarawak
09:15 - 09:35	**Anti-CDK4/6 therapy** Supported by Pfizer	**Dr. Nur Fadhlina** Clinical Oncologist, Universiti Malaya Medical Centre
09:35 - 09:55	**Somatostatin targeted therapy** Supported by Ipsen	**Dr. Wong Yoke Fui** Clinical Oncologist, Institut Kanser Negara
09:55 - 10:25	**Bone targeting agents** Supported by Amgen	**Dr. Soo Hoo Hwoei Fen** Clinical Oncologist, Hospital Pulau Pinang
10:25 - 10:35	**Q&A**	**All Speakers**
10:35 - 10:45	**Quiz**	

Plenary 5

Chairperson : **Carolyn Eng Chai Hui**

10:45 - 11:05	**Immune-checkpoint inhibitors** Supported by Roche	**Dr. Ang Soo Fan** Clinical Oncologist, Penang Adventist Hospital
11:05 - 11:25	**Immune-mediated toxicities** Supported by Roche	**Dr. Ibtisam Muhamad Nor** Clinical Oncologist, Hospital Kuala Lumpur
11:25 - 11:45	**Assessment of response in immunotherapy**	**Dr. Ibtisam Muhammad Nor** Clinical Oncologist, Hospital Kuala Lumpur
11:45 - 12:05	**Anti-ALK therapy** Supported by Novartis	**Dr. Junie Khoo Yu Yen** Clinical Oncologist, Hospital Umum Sarawak
12:05 - 12:25	**Treatment strategies for NTRK fusion positive solid tumours**	**Dr. Tan Chih Kiang** Clinical Oncologist, Hospital Umum Sarawak
12:25 - 12:35	**PARP inhibitors**	**Dr. Malwinder Singh Sandhu** Clinical Oncologist, Hospital Kuala Lumpur
12:35 - 12:45	**Q&A**	**All Speakers**
12:45 - 13:30	**HER2-targeted therapy** Lunch symposium supported by Roche	**Dr. Soo Hoo Hwoei Fen** Clinical Oncologist, Hospital Pulau Pinang
13:30 - 13:50	**BREAK**	

Plenary 6

Chairperson : **Dr Ooi Poh Lin**

13:50 - 14:20	**Endocrine therapy in Male Cancers** Tea symposium supported by Astellas	**Dr. Vincent Phua Chee Ee** Clinical Oncologist, Beacon Hospital
14:20 - 14:40	**Endocrine therapy in Female Cancers**	**Dr. Tan Ai Lian** Clinical Oncologist, Hospital Pulau Pinang
14:40 - 15:00	**Fertility issues and fertility sparing options**	**Assoc. Prof. Dr. Mukhri Hamdan** Gynaecologist, Universiti Malaya Medical Centre
15:00 - 15:10	**Q&A**	**All Speakers**

Plenary 7

Chairperson : **Dr Nur Fadhlina**

15:10 - 15:30	**Vascular access in systemic treatment**	**Prof. Dr. Anushya A/P Vijayanathan** Interventional Radiologist, UMMC
15:30 - 15:50	**Anti-coagulation - guide for oncologists**	**Dr. Henning Loo Cheng Kien** Haematologist, Universiti Malaya Medical Centre
15:50 - 16:10	**High dose chemotherapy**	**Prof. Dr. Bee Ping Chong** Haematologist, Universiti Malaya Medical Centre
16:10 - 16:30	**Extravasation**	**Yusmanatul Airah Bt Yusof** Oncology Sister, Universiti Malaya Medical Centre
16:30 - 16:40	**Q&A**	**All Speakers**
16:40 - 17:00	**Prizes & Closing**	

Roche

Anti-angiogenesis with Avastin

The Power of Proof

More than 12 positive pivotal trials across 7 cancer types[1-14]

Reference

1. Tewari KS, Sill MW, Penson RT, et al. *Improved survival with bevacizumab in advanced cervical cancer. New England Journal of Medicine.* 2014;370:734–743 **2.** Hurwitz H, Fehrenbacher L, Novotny W, et al. *Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer.* New England Journal 2004;350(23):2335-2342 **3.** Giantonio BJ, Catalano PJ, Meropol NJ et al. *Bevacizumab in combination with oxaliplatin, fluorouracil, and leucovorin (FOLFOX4) for previously treated metastatic colorectal cancer: results from the Eastern Cooperative Oncology Group Study E3200.* J Clin Oncol. 2007 Apr 20;25(12):1539-1544 **4.** Saltz LB, Clarke S, Díaz-Rubio E, et al. *Bevacizumab in Combination With Oxaliplatin-Based Chemotherapy As First-Line Therapy in Metastatic Colorectal Cancer: A Randomized Phase III Study.* Journal of Clinical Oncology. 2008;26(12):2013-2019. **5.** Bennouna J, Sastre J, Arnold D et al. *Continuation of bevacizumab after first progression in metastatic colorectal cancer (ML18147): a randomised phase 3 trial.* Lancet Oncol. 2013;14(1):1-9 **6.** Sandler A, Gray R, Perry MC, et al. *Paclitaxel-carboplatin alone or with bevacizumab for non-small-cell lung cancer.* N Engl J Med 2006;355:2542-2550 **7.** Reck M, Pawel J, Zatloukal P, et al. *Phase III Trial of Cisplatin Plus Gemcitabine with Either Placebo or Bevacizumab As First-Line Therapy for Non-squamous Non-Small-Cell Lung Cancer: AVAiL.* Journal of Clinical Oncology. 2009; 27(8): 1227-1234 **8.** Miller K, Wang M, Gralow J, et al. *Paclitaxel plus Bevacizumab versus Paclitaxel Alone for Metastatic Breast Cancer.* New England Journal of Medicine. 2007;357(26):2666-2676. **9.** Burger RA, Brady MF, Bookman MA, et al. *Incorporation of bevacizumab in the primary treatment of ovarian cancer.* New England Journal of Medicine. 2011;365(26):2473–2483. **10.** Perren TJ, Swart AM, Pfisterer J, et al. *A phase 3 trial of bevacizumab in ovarian cancer.* N Engl J Med. 2011;365(26):2484–2496 **11.** Aghajanian C, Blank SV, Goff BA, et al. *OCEANS: a randomized, double-blind, placebo-controlled phase III trial of chemotherapy with or without bevacizumab in patients with platinum-sensitive recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer.* J Clin Oncol. 2012;30:2039–2045 **12.** Escudier B, Pluzanska A, Koralewski P, et al. *Bevacizumab plus interferon alfa-2a for treatment of metastatic renal cell carcinoma: a randomised, double-blind phase III trial.* The Lancet. 2007;370(9605):2103-2111 **13.** Avastin Summary of Product Characteristics(SmPC), 2013 **14.** Friedman HS, Prados MD, Wen PY, et al. *Bevacizumab alone and in combination with irinotecan in recurrent glioblastoma.* J Clin Oncol 2009; 27: 4733– 4740

Basic Succinct Statement

Trade name: AVASTIN®

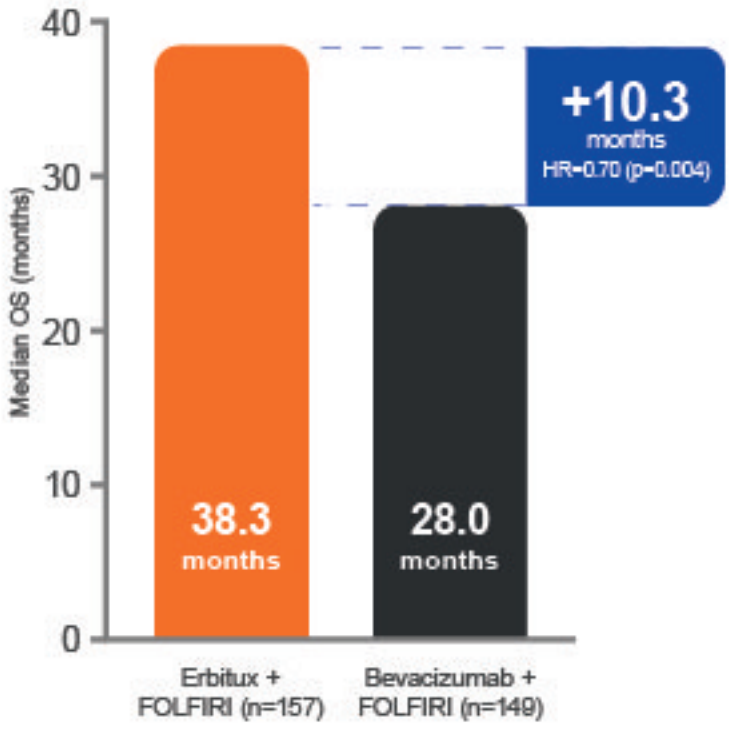
Active Ingredient: Bevacizumab

Therapeutic indications: mCRC: Avastin (bevacizumab) in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum. mBC: Avastin in combination with paclitaxel is indicated for first-line treatment of patients with metastatic breast cancer. NSCLC: Avastin, in addition to platinum-based chemotherapy, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer. mRCC: Avastin in combination with interferon alfa-2a is indicated for first-line treatment of advanced and/or metastatic renal cell cancer. GBM: Avastin is indicated for the treatment of glioblastoma with progressive disease following prior therapy as a single agent. The effectiveness of Avastin in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with Avastin. OC: Front-line: Avastin, in combination with carboplatin and paclitaxel in advanced (FIGO* stages III B, III C, and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Recurrent Platinum-Sensitive: Avastin, in combination with carboplatin and gemcitabine is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF*-targeted angiogenesis inhibitors. Recurrent Platinum-Resistant: Avastin in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin in patients who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents. CC: Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix. **Dosage and Administration**: mCRC The recommended dose of Avastin, administered as an infusion, is either 5 mg/kg or 10 mg/kg of body weight given once every 2 weeks or 7.5 mg/kg or 15 mg/kg of body weight given once every 3 weeks.It is recommended that treatment be continued until progression of the underlying disease or until unacceptable toxicity. mBC: The recommended dose of Avastin is 10mg/kg of body weight given once every 2 weeks or 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion.It is recommended that Avastin treatment be continued until progression of the underlying disease. NSCLC: Avastin is administered in addition to platinum-based chemotherapy for up to 6 cycles of treatment followed by Avastin as a single agent until disease progression. The recommended dose of Avastin when used in addition to cisplatin-based chemotherapy is 7.5 mg/kg of body weight given once every 3 weeks as an intravenous infusion. The recommended dose of Avastin when used in addition to carboplatin-based chemotherapy is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion. mRCC: 10 mg/kg every 2 weeks. GBM: 10 mg/kg every 2 weeks. OC: Front-line: 15 mg/kg of body weight given once every 3 weeks when administered in addition to carboplatin and paclitaxel for up to six cycles of treatment followed by continued use of Avastin as single agent for 15 months or until disease progression, whichever occurs earlier. Recurrent Platinum-Sensitive: 15 mg/kg of body weight given once every 3 weeks when administered in combination with carboplatin and gemcitabine for 6 cycles and up to 10 cycles followed by continued use of Avastin as single agent until disease progression. Recurrent Platinum resistant: 10 mg/kg body weight given once every 2 weeks when administered in combination with one of the following agents – paclitaxel, topotecan (given weekly) or pegylated liposomal doxorubicin. Alternatively, 15 mg/kg every 3 weeks when administered in combination with topotecan given on days 1-5, every 3 weeks. It is recommended that treatment be continued until disease progression. CC: Avastin is administered in combination with one of the following chemotherapy regimens: paclitaxel and cisplatin or paclitaxel and topotecan (see section 3.1.2 study GOG-0240 for further details on the chemotherapy regimens). The recommended dose of Avastin is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion. It is recommended that Avastin treatment be continued until progression of the underlying disease. **Contraindications**: Hypersensitivity to any components of the product, Chinese hamster ovary cell products, recombinant human or humanised antibodies. **Warnings and Precautions**: GI perforations; Fistulae; Hemorrhage; Pulmonary hemorrhage/Hemoptysis; Hypertension; Posterior Reversible Encephalopathy Syndrome; Arterial and venous thromboembolism; Congestive heart failure; Neutropenia; Wound healing; Necrotising fasciitis secondary to wound healing complications, gastrointestinal perforation or fistula formation; Proteinuria; Hypersensitivity; Infusion reactions; Immunogenecity. **Pregnancy and Lactation**: Avastin should not be used in pregnancy. In women with childbearing potential, appropriate contraceptive measures are recommended during Avastin therapy; and for at least 6 months following the last Avastin dose. **Undesirable Effects**: Leukopenia, Diarrhea, Neutropenia, Sepsis, Abscess, Infection, Cerebral ischemia, Syncope, Congestive cardiac failure, Arterial thromboembolism, Deep vein thrombosis, Dyspnea, Abdominal pain, Gastrointestinal disorder, Asthenia, Proteinuria, Gastrointestinal perforation, Wound healing delay, Hypertension, Hemorrhage, Epistaxis. **Packaging**: Vials of 400mg/16ml or Vials of 100mg/4ml

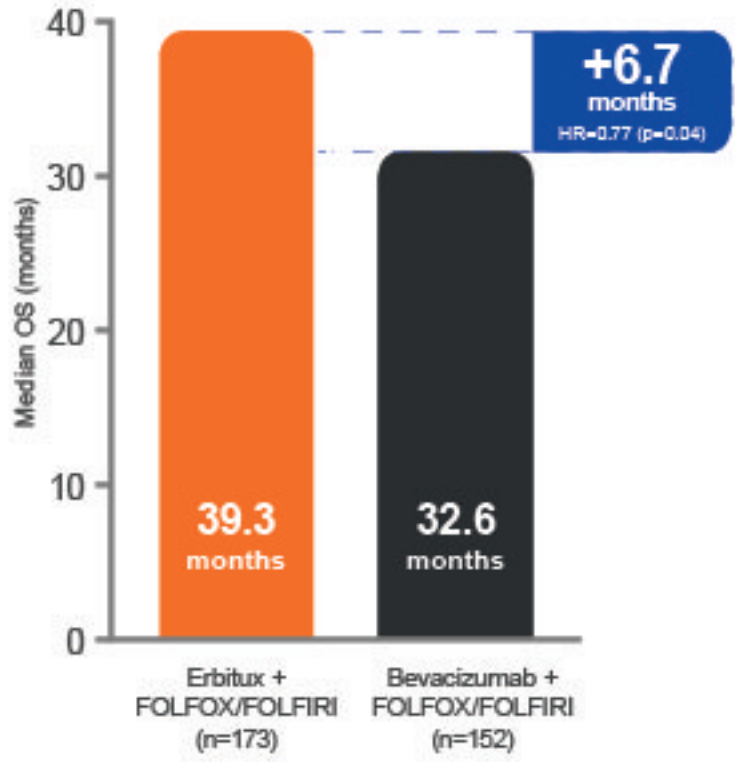
Full details on composition, indications, drug interactions, side-effects, dosage and precautions are available on request (MYAvastin0915/CD533.0)

Erbitux is the only 1st-line therapy, in combination with FOLFOX or FOLFIRI, demonstrating unprecedented survival benefit over bevacizumab + CT in Phase III trials* in patients with left-sided RAS wt mCRC*†‡1–3

Phase III FIRE-3†1
(Retrospective analysis of patients with left-sided RAS wt mCRC)



Phase III CALGB/SWOG 80405‡2
(Retrospective analysis of patients with left-sided RAS wt mCRC)



Patients with left-sided RAS wt mCRC recommended with Erbitux + FOLFOX or FOLFIRI in 1st-line, irrespective of treatment goal[1-5]

CT, chemotherapy; HR, hazard ratio; mCRC, metastatic colorectal cancer.

* Retrospective analyses of Phase III data.

†FIRE-3 did not meet its primary endpoint of significantly improving overall response rate based on investigators' read in patients with KRAS (exon 2) wt mCRC.[6] ‡The CALGB/SWOG 80405 study did not meet its primary endpoint of significantly improving overall survival in the Erbitux + CT arm vs bevacizumab + CT arm in patients with KRAS (exon 2) wt mCRC.[7]

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Abbreviated prescribing information: Product name: ERBITUX (cetuximab) 5mg/ml solution for infusion.Presentation: Each glass vial contains 20 ml. Excipients: sodium chloride, glycine, polysorbate 80, citric acid monohydrate, sodium hydroxide, water for injections. Indications: Treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer (mCRC): in combination with chemotherapy, or as a single agent in patients who have failed oxaliplatin and irinotecan-based therapy and who are intolerant to irinotecan. Treatment of patients with squamous cell cancer of the head and neck (SCCHN): in combination with radiation therapy for locally advanced disease or in combination with platinum-based chemotherapy for recurrent and/or metastatic disease. Dosage and administration: Administer ERBITUX once a week. Initial dose 400 mg/m2 infused over 120 mins; subsequent weekly doses 250 mg/m2 infused over 60 mins. Maximum infusion rate must not exceed 10 mg/min. Administration must be supervised by a physician experienced in antineoplastic therapy. Closely monitor the patient throughout the infusion and for at least 1 hour afterwards. Resuscitation equipment must be ensured. Prior to first infusion patients must receive premedication with an antihistamine and a corticosteroid; premedication recommended for all subsequent infusions. *ERBITUX 5mg/ml: Administer intravenously with an infusion pump, gravity drip or a syringe pump. Administer ERBITUX first and do not administer chemotherapeutic agents earlier than 1 hour after the end of the ERBITUX infusion. mCRC: ERBITUX should be continued until progression of the underlying disease. SCCHN locally advanced disease: Start ERBITUX therapy one week before radiation therapy and continue until the end of the radiation period. SCCHN recurrent and/or metastatic disease: Administer ERBITUX in combination with platinum-based chemotherapy followed by ERBITUX as maintenance therapy until disease progression. Special Populations: No dose adjustment required in the elderly (experience limited in patients older than 75 years). Safety and efficacy in paediatric population below the age of 18 years not established. Only patients with adequate renal, hepatic and hematological parameters have been investigated. Contraindications: Known severe hypersensitivity (grade 3 or 4) reactions to ERBITUX. The combination of ERBITUX with oxaliplatin-containing chemotherapy is contraindicated for patients with mutant RAS metastatic colorectal cancer (mCRC) or for whom RAS mCRC status is unknown. Contraindications for concomitantly used chemotherapeutic agents or radiation therapy must be considered. Special warnings and precautions: Infusion related reactions: Severe infusion-related reactions to ERBITUX have been reported. They occur usually during the first infusion and up to 1 hour after the end of infusion, but may occur after several hours or with subsequent infusions. Occurrence of a severe infusion-related reaction requires immediate and permanent discontinuation of ERBITUX and may necessitate emergency treatment. Decrease infusion rate if mild or moderate infusion-related reaction occurs and use lower rate in all subsequent infusions. Closely monitor patients with reduced performance status and pre-existing cardio-pulmonary disease. Skin reactions: Interrupt treatment if patient experiences a severe skin reaction (≥grade 3 NCI-CTC). Only resume if reaction resolves to grade 2. With second or third occurrence of severe skin reactions, resume at lower dose (200 mg/m2 after second occurrence, 150 mg/m2 after third occurence) only if reaction resolves to grade 2. A fourth occurrence of severe skin reaction, or failure to resolve to grade 2 during interruption, requires permanent discontinuation of ERBITUX. Respiratory disorders: If interstitial lung disease is diagnosed, ERBITUX must be discontinued and patient be treated appropriately. Electrolyte disturbances: Severe hypomagnesaemia has been observed. Hypomagnesaemia is reversible following discontinuation of ERBITUX. Hypokalaemia may occur as a consequence of diarrhea . Hypocalcaemia may also occur; in particular in combination with platinum-based chemotherapy the frequency of severe hypocalcaemia may be increased. Determination of serum electrolyte levels is recommended prior to and periodically during ERBITUX treatment. Electrolyte repletion is recommended, as appropriate. Neutropenia and related infectious complications: Patients who receive ERBITUX in combination with platinum-based chemotherapy are at an increased risk for the occurrence of severe neutropenia, which may lead to subsequent infectious complications such as febrile neutropenia, pneumonia or sepsis. Careful monitoring is recommended in such patients, in particular in those who experience skin lesions, mucositis or diarrhoea that may facilitate the occurrence of infections. Cardiovascular disorders: An increased frequency of severe and sometimes fatal cardiovascular events and treatment emergent deaths has been observed in the treatment of non-small cell lung cancer, squamous cell carcinoma of the head and neck and colorectal carcinoma. When prescribing ERBITUX, the cardiovascular and performance status of the patients and concomitant administration of cardiotoxic compounds such as fluoropyrimidines should be taken into account. Eye disorders: Patients presenting with signs and symptoms suggestive of keratitis should be referred promptly to an ophthalmology specialist. If a diagnosis of ulcerative keratitis is confirmed, treatment with ERBITUX should be interrupted or discontinued. If keratitis is diagnosed, the benefits and risks of continuing treatment should be carefully considered. ERBITUX should be used with caution in patients with a history of keratitis, ulcerative keratitis or severe dry eye. Contact lens use is also a risk factor for keratitis and ulceration. mCRC with RAS mutated tumour: ERBITUX should not be used in the treatment of colorectal cancer patients whose tumours have RAS mutations or for whom RAS tumour status is unknown. Results from clinical studies show a negative benefit-risk balance in tumours with RAS mutations. Pregnancy and lactation: Only use during pregnancy or as woman not employing adequate contraception if the potential benefit justifies potential risk to fetus. Breast-feeding during treatment with ERBITUX and for 2 months after the last dose is not recommended. Undesirable effects: Very common (≥1/10): skin reactions, hypomagnesaemia, mild or moderate infusion-related reactions, mild to moderate mucositis, which may lead to epistaxis, increase in liver enzyme levels. Common (≥1/100, <1/10): headache, conjunctivitis, diarrhea, nausea, vomiting, fatigue, dehydration, hypocalcaemia, anorexia, weight decrease, severe infusion-related reactions. Uncommon (≥1/1000, <1/100): blepharitis, keratitis, deep vein thrombosis, pulmonary embolism, interstitial lung disease. Frequency not known: superinfection of skin lesions with subsequent complications, aseptic meningitis. In combination with platinum-based chemotherapy, the frequency of severe leukopenia or severe neutropenia may be increased, and thus may lead to a higher rate of infectious complications such as febrile neutropenia, pneumonia and sepsis compared to platinum-based chemotherapy alone. In combination with fluoropyrimidines, the frequency of cardiac ischaemia including myocardial infarction and congestive heart failure as well as the frequency of hand-foot syndrome were increased compared to that with fluoropyrimidines. In combination with local radiation therapy of the head and neck area, additional undesirable effects were those typical of radiation therapy (such as mucositis, radiation dermatitis, dysphagia or leucopenia, mainly as lymphocytopenia). Reporting rates of severe acute radiation dermatitis, mucositis, late radiation-therapy related events were slightly higher in combination with ERBITUX. Interactions: In combination with platinum-based chemotherapy, the frequency of severe leukopenia or severe neutropenia may be increased, and thus may lead to a higher rate of infectious complications such as febrile neutropenia, pneumonia and sepsis compared to platinum-based chemotherapy alone. In combination with fluoropyrimidines, the frequency of cardiac ischaemia including myocardial infarction and congestive heart failure as well as the frequency of hand-foot syndrome were increased compared to that with fluoropyrimidines. In combination with capecitabine and oxaliplatin, the frequency of severe diarrhoea may be increased. Ref code: ER/V03/V0316

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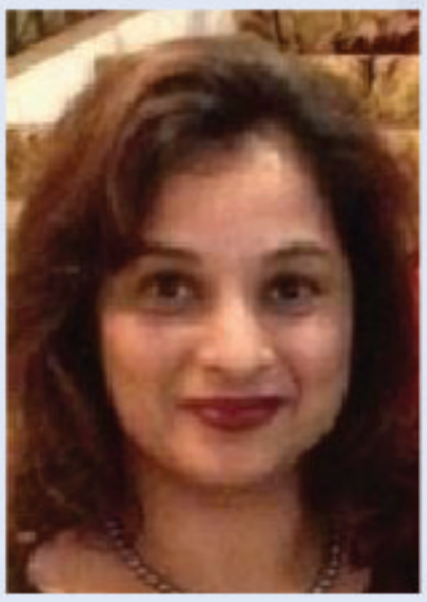
SPEAKERS
PROFILE

Dr. Ang Soo Fan
Consultant Medical Oncologist,
Penang Adventist Hospital.

Dr Ang was born and grown up in Penang. He completed his Bachelor Of Medicine And Surgery (MBBS) in University of Malaya then obtained the Membership Of Royal Colleges Of Physician of UK (MRCP). Subsequently, he received fellowship training in medical oncology at National Cancer Center Singapore. Dr Ang has special interest in gastrointestinal cancer, liver cancer and breast cancer.

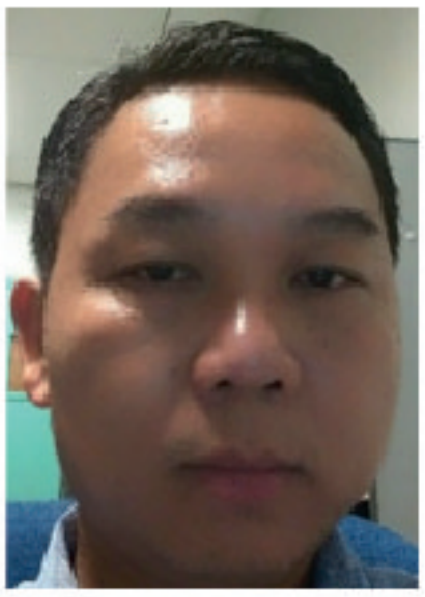


Prof Dr. Anushya Vijayananthan
Consultant Radiologist, Department of Biomedical Imaging,
University Malaya Medical Centre

Anushya Vijayananthan is an Associate Professor at the Department of Biomedical Imaging, University of Malaya. She completed her undergraduate studies at the University of Delhi in 1992 and then went on to complete her Master of Radiology (MRad) at the University of Malaya in 2001.

She subsequently did her training stints overseas in Vascular Ultrasound at the Thane Ultrasound Center, Mumbai in 2004 followed by a fellowship in Interventional Radiology at the Gartnavel General Hospital, Glasgow, UK in 2006. Her special interests include gynaecology and vascular ultrasound and interventional radiology. She also has a keen interest in MRgFUS (Magnetic Resonance guided Focussed Ultasound Surgery) especially for gynae pathologies. She is involved in medical education both undergraduate and post graduate and is the OSCE Coordinator for the faculty of medicine at University of Malaya.

She is currently also the Coordinator of the Continuing Biomedical Imaging Education Centre responsible for the organization of courses in the department.



Prof Dr. Bee Ping Chong

Consultant Hematologist, Medical department,
University Malaya Medical Centre

Prof Dr Bee is a Consultant Haematologist and a lecturer at the Faculty of Medicine, University of Malaya (UM) and the University of Malaya Medical Centre. He is a member of the Malaysian Medical Association, the Malaysian Society of Haematology and the European Society of Haematology. He has authored or co-authored many peer-reviewed journal articles and meeting abstracts in the field of Haematology. Assoc Prof Bee specialises in Haemato-Oncology (Myeloproliferative Disorders, Multiple Myeloma, Lymphomas, Leukaemias, myelodysplastic syndrome), non-Malignant Haematological disorders (bleeding disorders, Thrombosis and Anticoagulation, Anaemias, Idiopathic thrombocytopenic purpura, Haemoglobinopathy [Thalassaemia, Sickle Cell anaemia], paroxysmal nocturnal haemoglobinuria, thrombotic thrombocytopenic purpura) and haematopoietic stem cell transplantation/Bone marrow transplantation.

Carolyn Eng Chai Hui

Pharmacist, Pharmacy Department,
University Malaya Medical Centre

Graduated from Monash University (Aus) with Bachelor degree in Pharmacy in 2012. Had exposure to Australia Healthcare system through Professional Experience Placement, voluntary work and part-time employment. Begin working career in University Malaya Medical Centre in year 2013 as Pre-registered Pharmacist and was offered Registered Pharmacist position in year 2014. Worked as part of the outpatient pharmacy team in providing healthcare services to the public at the frontline in year 2014. Subsequently, has been practising under Inpatient Pharmacy Chemotherapy (IPC) unit which provides clinical pharmacy services to the Oncology and Haematology units of UMMC.

Prof. Dato' Dr. Fuad Bin Ismail

Consultant Clinical Oncologist,
Department of Radiotherapy & Oncology,
Universiti Kebangsaan Malaysia Medical Centre

Prof. Dr. Fuad Ismail obtained his medical degree from Universiti Kebangsaan Malaysia and completed oncology training in Glasgow, Scotland with the FRCR (UK) and the FFR (Ireland) in 1996. He serves as the Head of Department in PPUKM since 1999. He teaches and examines for the local Master of Clinical Oncology. He has worked on various projects with the International Atomic Energy Agency and Ministry of Health Malaysia. His research interests are namely breast, cervical and colo-rectal cancers, and is active as a clinical trialist in drug development. He has keen interest in value based medicine and availability of new drug for Malaysia.

Dr. Henning Loo

Consultant Haematologist, Department of Haematology, University Malaya Medical Centre

Graduated from UM 2004, MMed in Internal Medicine 2012 and hematologist 2017.

Dr. Ho Kean Fatt

Consultant Clinical Oncologist, Mount Miriam Cancer Hospital

Dr Ho started his medical education at the International Medical College (IMU), Kuala Lumpur and further his clinical training in Belfast, UK. After graduation from the Queen's University of Belfast in 1999, he continued his training as a physician and obtained his MRCP in 2002.

He was accepted into the Clinical Oncology training based in Birmingham and after obtaining his FRCR, he took on a 2 year Fellowship in Head and Neck IMRT at the Christies, Manchester. In the 2 years as a Clinical Research Fellow, he contributed several research publications in peer-reviewed journals. He obtained his research Medical Doctorate (MD) in Head and Neck Advance Radiotherapy from the University of Manchester in 2009. After working for over 10 years in UK, he returned as a Consultant Clinical Oncologist at Mount Miriam Cancer Hospital in 2010.

Dr. Ibtisam Muhamad Nor

Clinical Oncologist, Department of Radiotherapy & Oncology, Hospital Kuala Lumpur

Dr Ibtisam graduated from Royal College of Surgeons, Ireland in 2001 and completed her training in clinical oncology in University Malaya in 2012. She is currently a clinical oncologist at Hospital Kuala Lumpur.

Dr. Junie Khoo Yu Yen

Clinical Oncologist, Department of Clinical Oncology,
Hospital Umum Sarawak

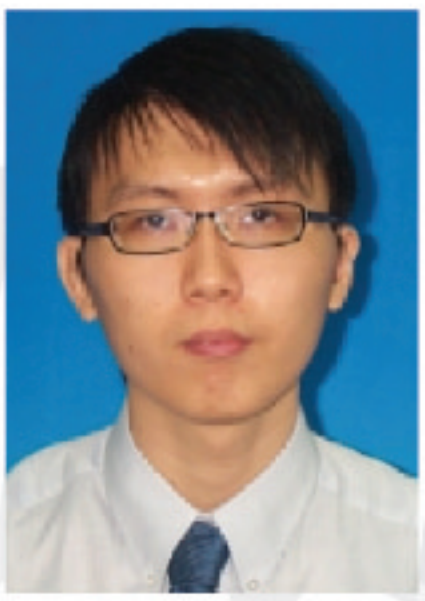
Dr Junie Khoo graduate from International Medical University (IMU) in 2005 and worked at Sabah for 6 years. Subsequently she attained Masters in Clinical Oncology (UM) in 2016 and is currently working as a Clinical Oncologist in Hospital Umum Sarawak, Kuching. She is involved in several multicentre trial as co- investigator and involved as core team in initiating SRS/SRT treatment in Hospital Umum Sarawak.

Dr. Khairiyah Sidek

Clinical Oncologist, Lecturer in Medicine and Clinical Oncologist,
Universiti Teknologi MARA (UiTM)

Dr Khairiyah graduated from University of Malaya with MBBS degree in 2007 then graduated in masters degree in Clinical Oncology in University if Malaya in 2017. She is currently a lecturer in Medicine and Clinical Oncologist: Universiti Teknologi MARA (UiTM), Faculty of Medicine, Sungai Buloh Campus. She is also a visiting clinical Oncologist to Hospital Canselor Tuanku Muhriz, Universiti Kebangsaan Malaysia Medical Centre.

Her research interests are in advanced radiation therapy, end of life care, systemic chemotherapy, holistic medicine, public health and medical education.



Lim Yong Yan

Pharmacist, Pharmacy Department,
University Malaya Medical Centre

Obtained Master of Pharmacy (MPharm) from University of Strathclyde in 2009. Completed provisional registration in University Malaya Medical Centre. Joined the pharmacy Central Intravenous Additive Service team (aka sterile complex) in 2012 as compounding pharmacist. Special interest in oncology and radiopharmacy.

Loong Ly Sia

Clinical Pharmacist, Pharmacy Department,
Universiti Kebangsaan Malaysia Medical Centre

Senior pharmacist serving at UKM Medical Centre with 15 years of work experience as inpatient pharmacist, clinical pharmacist to general medical units and currently to the hematology and bone marrow transplant units. Graduated with a Degree in Pharmacy (Hons) from University of Strathcylde (Glassgow) and later obtained a Masters in Clinical Pharmacy and Practice Policy (Distinction) from University College of London (UK) under a Commonwealth Scholarship. Current work includes overseeing medication safety activities, monitoring of drug therapy, providing clinical drug information, patient education, developing protocols and policies. Also works as clinical tutor and sessional lecturer in UKM and other universities. Currently a member of Malaysian Pharmaceutical Society, American College of Clinical Pharmacy and also has been a speaker in various local and national symposiums.

Dr. Malwinder Singh Sandhu

Clinical Oncologist, Department of Radiotherapy and Oncology,
Hospital Kuala Lumpur

Dr Malwinder Singh is a clinical oncologist in Radiotherapy and Oncology Department, Hospital Kuala Lumpur. He graduated from Melaka Manipal Medical College in 2006 with his MBBS degree. Subsequently he pursued his Masters in Clinical Oncology in University Malaya whereby he graduated in 2015. He actively participates as a principal investigator in various clinical trials conducted in Hospital Kuala Lumpur. He is also involved in multiple MDT such as gynaecology, urology, radiology, respiratory and SRS/SRT MDT.

Dr. Marfu'ah Nik Eezamuddeen

Clinical Oncologist, Faculty of Medicine,
University Teknologi Mara (UiTM)

Dr Marfu'ah graduated from University of Leicester, United Kingdom in 2007 and started her training in Warwickshire until 2011. She returned and completed her training in clinical oncology in University Malaya in 2015. She is currently a lecturer/clinical oncologist at University Teknologi Mara and Hospital Kuala Lumpur. She has a particular interest in thoracic malignancies and had been involved in research in many areas.

Dr. Mastura MD Yusof

Consultant Clinical Oncologist,
Pantai Hospital Kuala Lumpur, Subang Jaya Medical Centre

Dr. Mastura is Pantai Hospital Kuala Lumpur Head of Oncology Services, a consultant oncologist at Subang Jaya Medical Centre and a visiting lecturer for the Universiti Malaya Master in Clinical Oncology program. Her interests, clinical and research experiences encompass major tumour sites including breast, colorectal and lung. She has authored various articles in peer-reviewed journals, participated in various clinical trials, advisory and expert committee panels in cancer.

An executive council member of the Malaysian Oncological Society, she actively writes, delivers lectures and shares her expertise advocating for increasing cancer awareness, early diagnosis and improving treatment access and cancer outcome.

Dr. Mukhri Hamdan

Associate Professor and Consultant of Obstetrics and Gynaecology,
Subspecialist in Infertility and Reproductive Medicine/Surgery,

Department of Obstetrics and Gynaecology
Faculty of Medicine, University of Malaya
University Malaya Medical Centre

Associate Professor Dr Mukhri Hamdan, Consultant Obstetricians and Gynaecologists is a subspecialists in reproductive medicine and surgery. He was trained within Malaysia and the United Kingdom hospitals since 2003. After completing his master programme in 2010, Dr Mukhri practiced in UMMC as lecturer before he joined Complete Fertility Southampton UK where he gained advanced training in subfertility and reproductive medicine. He is certified by British Fertility Society to perform embryo transfer and intrauterine insemination. He also did his doctorate in Reproductive Medicine with particular interest in Endometriosis and IVF. In 2016, he was awarded a PhD from University of Southampton.

Dr. Muthukkumaran Thiagarajan

Clinical Oncologist, Department of Radiotherapy & Oncology
Hospital Kuala Lumpur

Dr Muthukkumaran obtained his Bachelor in Science (Medical Sciences) and Medical Doctor Degree from Universiti Putra Malaysia. His housemanship and medical officer rotations were in Sabah from 2004 – 2009. He then started formal training in Clinical Oncology at Universiti Malaya, Universiti Kebangsaan Malaysia and Hospital Kuala Lumpur as part of the Masters in Clinical Oncology programme, and graduated in 2013. He served as a Clinical Oncologist at Sabah Women and Children Hospital before his current post at Hospital Kuala Lumpur's Department of Radiotherapy and Oncology.Dr Muthukkumaran has a special interest in neuro-oncology, paediatric radiation and mesenchymal oncology. Besides participating in industry sponsored research, Dr Muthu also coordinates investigator initiated research among oncology medical officers in Hospital Kuala Lumpur. His administrative interests are radiotherapy resource management and value based medicine in oncology.

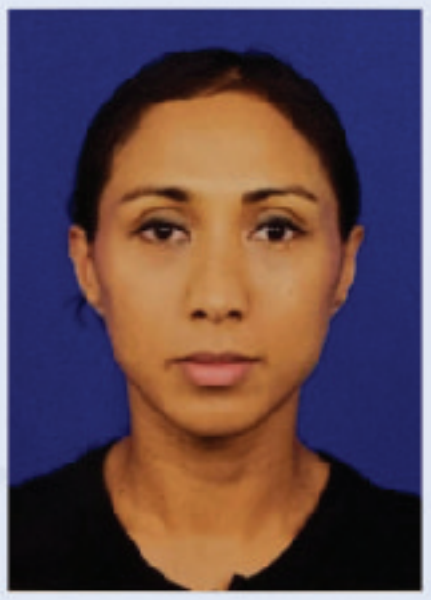
Dr. Nahjatul Kursyiah Binti Abd Ghafar

Clinical Oncologist, Radiotherapy & Oncology Department,
Hospital Wanita dan Kanak-kanak Sabah

Graduated from Cardiff University in 2006. Obtained Masters of Clinical Oncology from University Malaya in 2015. Worked as a specialist in Institut Kanser Negara from June 2015 to January 2016. And currently working in Hospital Wanita dan Kanak-kanak Sabah since February 2016. Special interest includes head & neck and lung cancer.

Dr Nur Fadhlina Abdul Satar

Consultant Clinical Oncologist, Clinical Oncology Department
University of Malaya Medical Centre



Dr Fadhlina is a consultant in clinical oncology at University Malaya Medical Centre, Kuala Lumpur. She graduated from University of Nottingham Medical School in 2006, and completed her MRCP in 2009. She was trained at University College London Hospital and Barts NHS Trust, and subsequently obtained FRCR and Masters in Clinical Oncology under Institute Cancer Research. She attained Certificate for Completion of Specialist Training (CCST) in 2017 from GMC (UK). Her interest in medical education has generated publication in Clinical Oncology journal, and web based learning tool on Royal College Radiologists website. Her clinical areas of interests are head and neck, breast and gastrointestinal cancers.

Dr. Soo Hoo Hwoei Fen

Clinical Oncologist, Department of Oncology and Radiotherapy,
Hospital Pulau Pinang

Dr Soo Hoo completed her FRCR training in The Christie NHS Foundation Trust, Manchester and since then she has worked as a clinical oncologist in Hospital Kuala Lumpur, Hospital Ipoh and Hospital Pulau Pinang. At the same time she is also the visiting oncologist to Hospital Alor Setar. She is involved with the National Curriculum Writing Group for Clinical Oncology and has spoken in multiple oncology workshops. Apart from that, she is principle investigators in multiple active clinical trials.

She received four years in medical training prior Oncology when she was involved in stem cell transplant for refractory severe auto-immune disorders. Dr Soo Hoo had successfully completed and defended her doctoral thesis titled “Cancer Targeted Therapy with Recombinant EGFR-histone-botulinum gene” in Chinese Academy of Medicine’s National Key Laboratory of Molecular Biology in year 2001.

Dr. Tan Ai Lian

Clinical Oncologist,
Hospital Pulau Pinang

Dr Tan Ai Lian graduated from Chinese Medical University, Taiwan. She was trained in Internal Medicine in National Taiwan University Hospital before returning to Malaysia to serve the public sector.

Dr Tan received her clinical oncology training in Penang General Hospital before being admitted as Fellow by Royal College of Radiologists in clinical (London) in2015. After that Dr.Tan continue her career in doing attachment in National Cancer Centre Singapore. Currently she is Clinical Oncologist in Penang General Hospital and is also the visiting oncologist in Hospital Alor Star. Her special interest is in the management of head and neck cancers and has published widely in peer review journal. She is currently also actively in running few trials in Penang General Hospital.

Dr. Tan Chih Kiang

Clinical Oncologist, Radiotherapy & Oncology Department,
Hospital Umum Sarawak

Dr Tan Chih Kiang graduated with MBBS from International Medical University in 2005 and subsequently obtained his Masters in Clinical Oncology from University Malaya in 2017. He is currently practising as a clinical oncologist at Sarawak General Hospital.

Tan Wen Chieh

Pharmacist, Manufacturing Unit, Pharmacy Department,
Universiti Malaya Medical Center

Graduated from University Science Malaysia (USM) in 2005. Started as Provisionally Registered Pharmacist in University Malaya Medical Centre (UMMC) in June 2005. Then was employed by UMMC on June 2006 as Outpatient Pharmacist. In 2008, become Cytotoxic Drug Reconstitution (CDR) Pharmacist. Have been involved in quality management and clinical trials since then. In April 2015, was appointed as Head of Manufacturing Unit, Pharmacy Department which involve in non sterile and sterile manufacturing of drugs.

Dr. Vaishnavi Jeyasingam

Clinical Oncologist, Department of Radiotherapy and Oncology, Hospital Kuala Lumpur

Dr Vaishnavi Jeyasingam graduated with MBBS from Universiti of Malaya, in 2005 and was awarded the Dean's List. She obtained her Masters in Clinical Oncol0gy from the same institution in 2013. She has worked as a medical officer in the Palliative Care Unit in Selayang Hospital prior to her postgraduate studies. As a Clinical Oncologist, she has served in the Oncology Department of Hospital Sultan Ismail, Johor Bahru. She is currently a clinical oncologist at the Radiotherapy and Oncology Department in Hospital Kuala Lumpur since the year 2014.

Dr Vaishnavi also underwent a clinical attachment with the Head and Neck Radiation unit at the Princess Alexandra Hospital in Brisbane, Australia. Her areas of special interest are head and neck radiation, lymphomas and gastrointestinal stromal tumours. She also is the Oncology representative in the hospital Pain Free Committee and supervisor for the Masters in Clinical Oncology training.

Dr. Vincent Phua Chee Ee

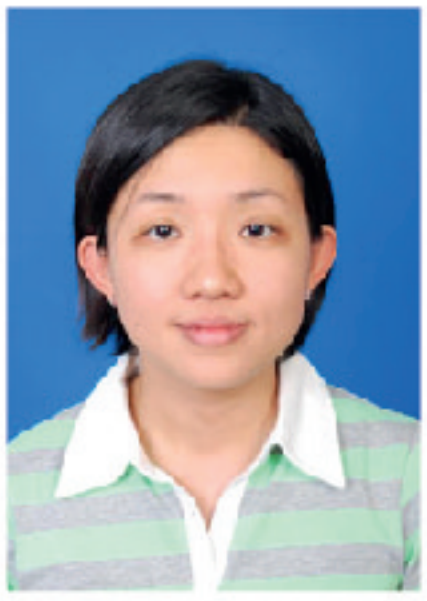
Consultant Oncologist,
Beacon Hospital

Dr Vincent Phua graduated from University of Melbourne in 2000 and obtained his first specialist qualification in Clinical Oncology in 2007 from FRCR (UK). He then completed his Masters in Clinical Oncology in 2008 (UM). He is currently working at Beacon International Specialist Centre and has special interest in advanced radiotherapy techniques including SRS/SRT, SBRT and IMRT.

Assoc Prof Dr. Wan Zamaniah Binti Wan Ishak

Consultant Clinical Oncologist,
Clinical Oncology Unit, Faculty of Medicine, UM

Associate Prof.Dr. Wan Zamaniah is a Consultant Clinical Oncologist at the University Malaya Medical Centre and University Malaya Specialist Centre, Kuala Lumpur, Malaysia. She graduated from University of Malaya, Kuala Lumpur Malaysia with Bachelor of Medicine & Bachelor of Surgery & completed post graduate training in Clinical Oncology in 2010. Being a supervisor and coordinator for Master of Clinical Oncology programme as well as the University Malaya Medical programme at the Faculty of Medicine, University Malaya Medical Centre, she is actively involved in the teaching, research and training of the future clinical oncologists and future doctors. She published some of her works in the areas involved. She speaks in her areas of interest in both local and international scientific conferences.



Dr. Wong Yoke Fui

Consultant Oncologist,
Institusi Kanser Negara

Dr Wong obtained her MBBS degree fron University Malaya in 2005 and completed Master of Clinical Oncology training in 2014. She is currently the Head of Clinical Research Center in National Cancer Institute. She is a respected member of Clinical Practice Guideline for Nasopharyngeal Carcinoma (Malaysia) Development Group 2017. She is also an Expert Committee for The effect of Chinese Herbal Medicine as an Adjunct Management of Fatigue and Muscle Weakness in Cancer Patient Receiving Chemotherapy under Health Technology Assessment.

Yusmanatul Airah Bt Yusof

Head Nurse, Clinical Oncology & Medical Day Care & OPAT,
Nursing Department, University Malaya Medical Centre

Yusmanatul Airah Bt Yusof is now the Head Nurse at Clinical Oncology & Medical Daycare & OPAT, University Malaya Medical Centre. Her academic qualifications include Advanced Diploma in Oncology Care Nursing. She previously served in: Pschiatric Ward for 6 months in 1996-Mei 1997, Medical Ward from 1997-2016, Adult Bone Marrow Transplant from 2000-2016, Promoted to be Nurse Manager in 2011-2016 in Haematology Ward, Surgery Ward Nurse Manager from 2016 -2018 and Hemato-Oncology Day Care Head Nurse from November 2018 till now.

RAPID POWER

THAT REDEFINES FIRST LINE

Introducing KRYXANA
A new CDK4/6 inhibitor
for the treatment of
HR+/HER2- locally
advanced or metastatic
breast cancer

Indicated for use in combination with any aromatase inhibitor

KRYXANA in combination with an aromatase inhibitor is indicated for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer as initial endocrine-based therapy.

KRYXANA® Basic Succinct Statement

Important note: Before prescribing, consult full prescribing information.

Presentation: Film-coated tablets (FCT) containing 200 mg of ribociclib.

Indications: Kryxana® is indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Dosage and administration:

Adults: The recommended dose of Kryxana is 600 mg (3 x 200 mg FCT) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days.

Special populations: • *Hepatic impairment:* Mild: No dose adjustment is necessary. Moderate or severe: Dose adjustment is required, and the starting dose of 400 mg is recommended. • *Pediatrics:* Safety and efficacy have not been established.

Contraindications: • Patients with hypersensitivity to the active substance or to peanut, soya or any of the excipients.

Warnings and precautions: • Based on the severity of the neutropenia, Kryxana may require dose interruption, reduction, or discontinuation. • Liver function tests (LFTs) should be performed before initiating therapy with Kryxana. Based on the severity of transaminase elevations, Kryxana may require dose interruption, reduction, or discontinuation. • The ECG should be assessed prior to initiation of treatment. Treatment with Kryxana should be initiated only in patients with QTcF values <450 msec. The ECG should be repeated at approximately Day 14 of the first cycle and at the beginning of the second cycle, then as clinically indicated. Appropriate monitoring of serum electrolytes (including potassium, calcium, phosphorous, and magnesium) should be performed prior to initiation of treatment, at the beginning of the first 6 cycles, and then as clinically indicated. Any abnormality should be corrected before the start of Kryxana therapy. Based on the observed QT prolongation during treatment, Kryxana may require dose interruption, reduction, or discontinuation.

Adverse drug reactions:

Very common (≥10%): Urinary tract infection, neutropenia, leukopenia, anaemia, lymphopenia, decreased appetite, headache, insomnia, dyspnoea, back pain, nausea, diarrhoea, vomiting, constipation, stomatitis, abdominal pain, alopecia, rash, pruritus, fatigue, peripheral oedema, pyrexia, abnormal liver function tests, leukocyte count decreased, neutrophil count decreased, haemoglobin decreased, lymphocyte count decreased, platelet count decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, phosphorous decreased, potassium decreased.

BSS KRYXANA RD 29 Dec 16; APPR 2 Apr 18

For Healthcare Professionals only
For full prescribing information, please contact:

NOVARTIS

Novartis Corporation (Malaysia) Sdn Bhd (10920H)
Level 22, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13,
46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.
Tel: 03-7948 1888 Fax: 03-7948 1818 www.novartis.com

KRYXANA®
ribociclib

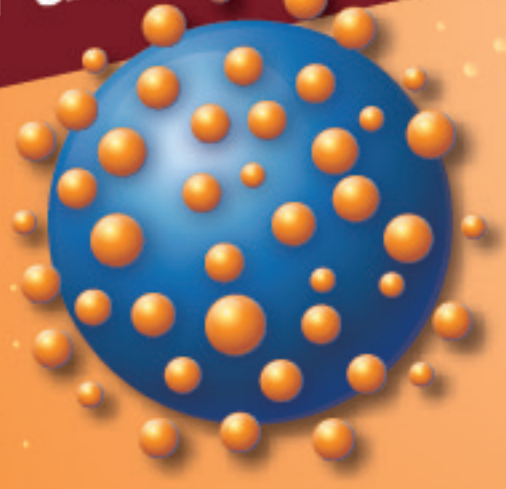
KRY.AMD.01/MY1811930188

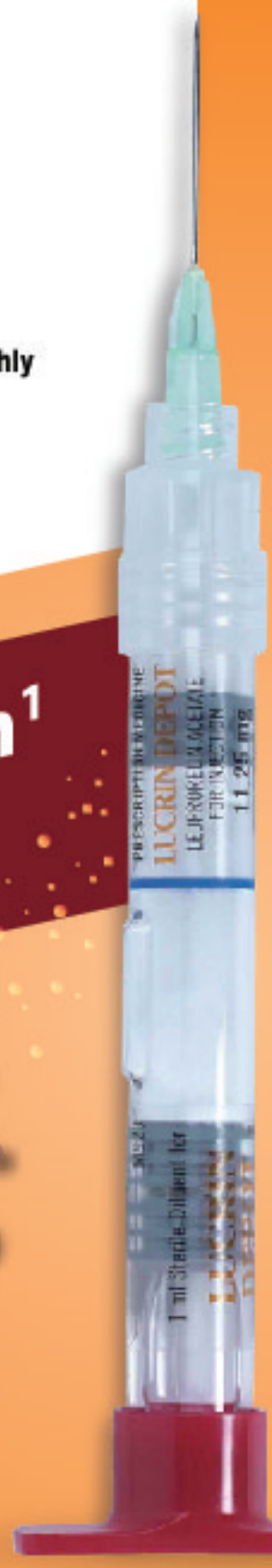
LUCRIN® DEPOT PDS

LEUPRORELIN ACETATE

3.75mg 1-Monthly, 11.25mg 3-Monthly, 30mg 6-Monthly

Less injection pain[1]
Ease of use[2]





23-25 Gauge needle

No need for local anesthetic

Dual choice[3,4]

of SC or IM injection for 1 and 3-monthly[3,4]

Luer lock device[3,4,5]

prevents leakage

Microsphere sustained-release technology[3,4,5]

maintains constant serum drug levels over 1, 3 and now 6 months[6,7]

Prefilled, dual-chamber syringe (PDS)[3,4,5]

No external mixing of ingredients is required
Reduced dosing and medication errors[2]

No refrigeration[3,4,5]

required for storage

An Innovation Built to Last

References: **1.** Williams, G, Lindsay, S, Bowsher, WG. Randomised crossover trial to assess the tolerability of LHRH analogue administration. *Prostate Cancer and Prostatic Dis.* 2003; 6: 187–189 **2.** Makwana, S, et al. Prefilled syringes: An innovation in parenteral packaging. *Int J Pharm Investig.* 2011; 1(4): 200-206 **3.** LUCRIN 11.25mg local package insert, 2017 **4.** LUCRIN 3.75mg local package insert, 2017 **5.** LUCRIN 30mg local package insert, 2016 **6.** Okada. One- and three-month release injectable microspheres of the LH-RH superagonist leuprorelin acetate. *Adv Drug Delivery Rev.* 1997; 28: 43–70 **7.** Tunn, UW. and Weckey, K. Safety and clinical efficacy of a new 6-month depot formulation of leuprorelin acetate in patients with prostate cancer in Europe. *Prostate Cancer and Prostatic Dis.* 2009; 12: 83–87 **8.** CDS-0367-1017 version 13.0

Abridged Prescribing Information

Lucrin® DEPOT 3.75MG Composition: Leuprolide Acetate **Indications: Prostate Cancer:** Palliative treatment of advanced prostatic cancer. **Endometriosis:** Treatment of endometriosis for a period of 6 months. It can be used as sole therapy or as an adjunct to surgery. **Uterine Fibroids:** Treatment of anemia caused by uterine leiomyomata in woman who fail iron therapy. **Breast Cancer:** Treatment of breast cancer in premenopausal woman in whom hormone therapy is specified. **Paediatric use - Central Precocious Puberty (CPP)** Treatment of children with Central Precocious Puberty. **Dosage:** Depot inj 3.75 mg monthly. **Paediatric use - Central Precocious Puberty (CPP):** The recommended starting dose is 0.3 mg/kg for four weeks (minimum 7.5 mg). **Contraindication:** Known hypersensitivity to leuprorelin acetate, similar nonapeptides, or any of the excipients; Pregnancy **Special Precautions:** Changes in bone mineral density. Convulsion. Transient worsening of prostate cancer symptoms may occur during first few weeks of administration, i.e bone pain, spinal cord compression, Hyperglycemia, Increased risk of myocardial infection, stroke, effect on QT/QTc interval, Increase of sex steroids during early phase of therapy, Inadequate control of pubertal process due to non compliance or inadequate dosing, Not to be used by nursing mother. **Adverse Reactions:** prostate tumour flare, aggravation of prostate cancer, weight gain, weight loss, loss or decreased libido, increase libido, headache, muscular weakness, vasodilation, hot flushes, hypotension, orthostatic hypotension, dry skin, hyperhydrosis, rash, urticaria, hair growth abnormal, hair disorder, night sweats, hypotrichosis, pigmentation disorder, cold sweat, hirsutism, gynaecomastia, breast tenderness, erectile dysfunction, testicular pain, breast enlargement, breast pain, prostate pain, penile swelling, penis disorder, testis atrophy, mucosal dryness, diabetes mellitus, glucose tolerance impaired, total cholesterol increased, LDL increased, triglycerides increased, osteoporosis, feeling hot, irritability, acne, eczema, nail disorder, vaginal discharge, genital discharge, vaginal hemorrhage, dysmenorrhea, menstrual disorder, breast atrophy, breast engorgement, metrorrhagia, menopausal symptoms, galactorrhea, dyspareunia, uterine disorder, vaginitis, menorrhagia, affects lability, rash including erythema multiforme, pain, injection site reactions including abscess **P/P:** Depot inj 3.75 mg x 1's. Reference: MY PI Feb 2017 CDS0303671114 **Lucrin® DEPOT 11.25MG Composition:** Leuprolide Acetate **Indications: Prostate Cancer:** Palliative treatment of advanced prostatic cancer. **Endometriosis:** Treatment of endometriosis for a period of 6months. It can be used as sole therapy or as an adjunct to surgery. **Uterine Fibroids:** treatment of leiomyoma uteri (uterine fibroids) for a period up to 6 months. Therapy may be preoperative prior to myomectomy or hysterectomy, or it may provide symptomatic relief for the perimenopausal woman who does not desire surgery. **Breast Cancer:** Treatment of breast cancer in pre and peri-menopausal woman in whom hormone therapy is specified. **Dosage:** Depot inj 11.25 mg every 3 months. **Contraindication:** Known hypersensitivity to leuprorelin acetate, similar nonapeptides, or any of the excipients. **Special Precautions:** Changes in bone mineral density, Convulsion, Transient worsening of prostate cancer symptoms may occur during first few weeks of administration, i.e bone pain, spinal cord compression, Hyperglycemia, Increased risk of myocardial infection, stroke, effect on QT/QTc interval, Increase of sex steroids during the early phase of treatment, Not to be used by nursing mother. **Adverse Reactions:** prostate tumour flare, aggravation of prostate cancer, weight gain, weight loss, loss or decreased libido, increase libido, headache, muscular weakness, vasodilation, hot flushes, hypotension, orthostatic hypotension, dry skin, hyperhydrosis, rash, urticaria, hair growth abnormal, hair disorder, night sweats, hypotrichosis, pigmentation disorder, cold sweat, hirsutism, gynaecomastia, breast tenderness, erectile dysfunction, testicular pain, breast enlargement, breast pain, prostate pain, penile swelling, penis disorder, testis atrophy, mucosal dryness, diabetes mellitus, glucose tolerance impaired, total cholesterol increased, LDL increased, triglycerides increased, osteoporosis, feeling hot, irritability, acne, eczema, nail disorder, vaginal discharge, genital discharge, vaginal hemorrhage, dysmenorrhea, menstrual disorder, breast atrophy, breast engorgement, metrorrhagia, menopausal symptoms, galactorrhea, dyspareunia, uterine disorder, vaginitis, menorrhagia, affects lability. **P/P:** Depot inj 11.25 mg x 1's. Reference: MY PI Jan 2017 CDS0303671114 **Lucrin® 6 MONTH DEPOT 30mg INJECTION Composition:** Leuprorelin Acetate **Indications:** Lucrin® Depot for injection is indicated in the palliative treatment of advanced prostatic cancer. **Dosage:** Depot inj 30 mg every 6 months. **Contraindication:** Known hypersensitivity to leuprorelin acetate, similar nonapeptides, or any of the excipients **Precautions:** Initially causes increase in serum levels of testosterone. Urinary tract obstruction, metastatic vertebral lesions, reversible bone loss with depot inj. Hyperglycaemia and increased risk of developing diabetes. Myocardial infarction, sudden cardiac death and stroke. QT prolongation, convulsions, effects on fertility. **Adverse Reactions:** Anaemia, increased appetite, libido decreased, heart failure, flushing, hyperlipidaemia, erectile dysfunction, testicular atrophy, fatigues, injection site reaction, injection site inflammation, injection site pain, injection site induration, injection site erythema, injection site abscess, injection site swelling, transaminase increased **P/P:** Depot inj 30 mg x 1's. Reference: MY PI 11 Apr 2016

Full prescribing information is available upon request.

For Medical/Healthcare Professionals only.

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Abbvie Sdn Bhd (987315-T)
8th Floor Menara Lien Hoe, No 8 Persiaran Tropicana, 47410 Petaling Jaya, Selangor Darul Ehsan, Malaysia.
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MY-LUCR-180027 14112018

Halaven® (eribulin mesilate) Injection

LENVIMA® (lenvatinib) capsules
RESPONSE THAT MATTERS

HALAVEN STANDS FOR **SURVIVAL** IN TWO TUMOUR TYPES[1,2]

HALAVEN® monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease (see CLINICAL STUDIES). Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments.

NEW INDICATION

HALAVEN® is indicated as monotherapy for the treatment of locally advanced or metastatic HER2 negative breast cancer after failure of one chemotherapeutic regimen for advanced disease. Patients should have received an anthracycline and a taxane unless these treatments were not suitable.[4]

NEW INDICATION

HALAVEN® indicated for the treatment of inoperable liposarcoma after progression following prior chemotherapy for advanced or metastatic disease in adults. Patients should have received two previous chemotherapy treatments, one of which should have included an anthracycline unless this treatment is unsuitable.[4]

Lenvima is a multitargeted tyrosine kinase inhibitor (TKI) with a new Type V Kinase binding mode[5, 6]

LENVIMA® is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, Differentiated (papillary/follicular/Hürthle cell) Thyroid Carcinoma (DTC), Refractory to Radioactive Iodine (RAI)

NEW INDICATION

LENVIMA® is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy

Reference: 1. Cortes J, O'Shaughnessy J, Loesh D, et al: Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomized study. Lancet 2011;377:914-923. **2.** Schöffski P, et al. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomised, open-label, multicentre, phase 3 trial. Lancet 2016;387:1629-37. **3.** Schlumberger M et al. Lenvatinib versus placebo in 131I-refractory differentiated thyroid cancer. NEJM 2015; 372: 621-30. **4.** Approval letter from National Pharmaceutical Regulatory Agency, Bil (53) dlm. BPFK/PPP/07/04 Jld3. **5.** Okamoto K et al, ACS Medicinal Chemistry Letters 2015; 6(1):89-94. 6. Tohyama O, et al. J Thyroid Res, 2014; 2014: 638747

Abbreviated Prescribing Information

HALAVEN* (Eribulin mesylate) 0.5 mg/ml solution for injection. **Indications:** HALAVEN* is indicated as monotherapy for the treatment of locally advanced or metastatic HER2 negative breast cancer after failure of one chemotherapeutic regimen for advanced disease. Patients should have received an anthracycline and a taxane unless these treatments were not suitable. HALAVEN* is indicated for the treatment of inoperable liposarcoma after progression following prior chemotherapy for advanced or metastatic disease in adults. Patients should have received two previous chemotherapy treatments, one of which should have included an anthracycline, unless this treatment is unsuitable. **Dosage and Administration:** The recommended dose of HALAVEN* as is 1.4 mg/m2 which should be administered intravenously over 2-5 minutes on Days 1 and 8 of every 21-day cycle. The dose may be diluted in up to 100 ml of normal saline for injection. **Dose delays during therapy:** •Delay the administration of HALAVEN* on Day 1 or Day 8 for any of the following: •Absolute neutrophil count (ANC) < 1 x 109/L •Platelets < 75 x 109/l. •Grade 3 or 4 non-hematological toxicities. The recommended dose of HALAVEN* in patients with mild hepatic impairment (Child-Pugh A) is 1.1 mg/m2 administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle. The recommended dose of HALAVEN* in patients with moderate hepatic impairment is 0.7 mg/m2 administered intravenously over 2 to 5 mirvutes on Days 1 and 8 of a 21-day cycle. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients and breast feeding. **Warnings and Precautions:** Myelosuppression is dose dependent and primarily manifested as neutropenia. Treatment with HALAVEN* should only be initiated in patients with ANC values ≥ 1.5 x 109/L and platelets > 100 x 109/L. Patients experiencing febrile neutropenia, severe neutropenia or thrombocytopenia, should be treated. Patients with ALT or AST >3 x ULN experienced a higher incidence of Grade 4 neutropenia and febrile neutropenia. Peripheral neuropathy commonly occurs. Monitor patients for signs of peripheral motor and sensory neuropathy. Correct hypokalemia or hypomagnesemia prior to initiating HALAVEN* and monitor these electrolytes periodically during therapy. Avoid HALAVEN* in patients with congenital long QT syndrome. Some patients with moderately or severely impaired renal function (creatinine clearance <50 ml/min) may have increased eribulin exposure and may need a reduction of the dose. For all patients with renal impairment, caution and close safety monitoring is advised. Eribulin does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP2E1 or CYP3A4 enzymes or induce CYP1A2, CYP2C9, CYP2C19 or CYP3A4 enzymes at relevant concentrations. **Pregnancy and Lactation:** Women of childbearing age must be advised to avoid becoming pregnant whilst they or their male partner are receiving HALAVEN*. HALAVEN* should not be used during pregnancy unless clearly necessary. A risk to newborn or infants cannot be excluded and therefore HALAVEN* should not be used during breast feeding. **Adverse Reactions (all grades):** Neutropenia (53.6%), Leukopenia (27.9%), Anaemia (21.8%), Peripheral neuropathy (35.9%), Nausea (35.7%), Fatigue/Asthenia (53.2%). **Storage:** Do not store above 25°C). Date of revision: May 2018

LENVIMA* 4 mg hard capsules, 10 mg hard capsules. **Mechanism of action:** LENVIMA* is a receptor tyrosine kinase (RTK) inhibitor that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1 (FLT1), VEGFR2 (KDR), and VEGFR3 (FLT4), in addition to other proangiogenic and oncogenic pathway-related RTKs including fibroblast growth factor (FGF) receptors FGFR1, 2, 3, and 4, the platelet derived growth factor (PDGF) receptor PDGFRα, KIT, and RET. **Indications:** •LENVIMA* is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). •LENVIMA* is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. **Dosage and Administration:** DTC - The recommended daily dose of lenvatinib is 24 mg (two 10 mg capsules and one 4 mg capsule) once daily. The daily dose is to be modified as needed according to the dose/toxicity management plan. RCC - The recommended daily dose of lenvatinib is 18 mg (one 10 mg capsule and two 4 mg capsules) once daily in combination with 5 mg of everolimus once daily. The daily doses of lenvatinib and, if necessary, everolimus are to be modified as needed according to the dose/toxicity management plan. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** Hypertension, proteinuria, renal impairment (including renal failure), cardiac failure, Posterior reversible encephalopathy syndrome (PRES) / Reversible Posterior Leucoencephalopathy Syndrome (RPLS), hepatotoxicity, haemorrhagic events, arterial thromboembolic events (cerebrovascular accident, transient ischaemic attack, and myocardial infarction), gastrointestinal perforation or fistulae, QT interval prolongation, impairment of thyroid stimulating hormone suppression / thyroid dysfunction, diarrhoea, patients aged 75 years, patients of ethnic origin other than Caucasian or Asian. In some of these cases, dose interruptions, adjustments, or discontinuation may be necessary. There are no data on the use of LENVIMA* immediately following sorafenib or other anticancer treatments and there may be a potential risk for additive toxicities unless there is an adequate washout period between treatments. The minimal washout period in clinical trials was of 4 weeks. **Pregnancy and Lactation:** Women of childbearing potential should avoid becoming pregnant and use highly effective contraception while on treatment with LENVIMA* and for at least one month after finishing treatment.LENVIMA* should not be used during pregnancy unless clearly necessary.It is not known whether LENVIMA* is excreted in human milk. A risk to newborns or infants cannot be excluded and, therefore, LENVIMA* is contraindicated during breastfeeding. **Storage:** LENVIMA* is to be stored below 30°C. **Date of Revision of PI:** July 2018.

For healthcare professional only
Full prescribing information available on request

Eisai (Malaysia) Sdn. Bhd. (18039-D)
Lot 6.1, 6th Floor, Menara Lien Hoe, 8, Persiaran Tropicana, 47410, Petaling Jaya, Selangor, Malaysia
Tel:60-3-7803-9096 Fax:60-3-7803-0060

human health care

ML-ONC-TY-19A-01

A first-in-class CDK4/6 inhibitor for postmenopausal women with ER+ HER2- metastatic breast cancer.[1,2]

JOINING **FORCES**

IBRANCE™ + LETROZOLE

mPFS >2 YEARS IN FIRST-LINE SETTING

(24.8 months vs. 14.5 months with letrozole alone)[3]

IBRANCE + letrozole extends mPFS to >2 years

24.8 months vs. 14.5 months with letrozole alone (HR=0.58; 95% CI 0.46-0.72; 2-sided p<0.001).[3]

IBRANCE – associated adverse events are manageable with dose modification.

Dose modifications such as dose interruption, cycle delay or dose reduction can be applied based on individual's safety and tolerability.[1]

Convenient once-daily dosing with IBRANCE

IBRANCE (125 mg) once daily for 3 weeks on/1 week off plus letrozole (2.5 mg) once daily, continuously.[1]

IBRANCE + letrozole is recommended by the NCCN Guidelines®

as a first-line treatment for postmenopausal women with ER+HER2-metastatic breast cancer (category 2A).[4]

START IBRANCE WHEN YOU START LETROZOLE

IBRANCE® Abbreviated Product Information[1]

IBRANCE® (Palbociclib) capsules, oral. **PRESENTATION:** IBRANCE® 125mg, 100mg, and 75mg hard gelatin capsules. Available as a bottle of 21 capsules or a blister of 21 capsules. **INDICATIONS AND USAGE:** IBRANCE® is indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. The indication is approved based on progression-free survival. **DOSAGE AND ADMINISTRATION:** The recommended dose of IBRANCE® is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. IBRANCE® should be taken with food in combination with letrozole 2.5 mg once daily given continuously throughout the 28-day cycle. Patients should be encouraged to take their dose at approximately the same time each day. **CONTRAINDICATIONS:** None. **WARNINGS AND PRECAUTIONS:** NEUTROPENIA: Decreased neutrophil counts have been observed in clinical trials with IBRANCE®. Grade 3 (57%) or 4 (5%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole in the randomized clinical trial (Study 1).Febrile neutropenia events have been reported in the IBRANCE® clinical program, although no cases of febrile neutropenia have been observed in Study 1. INFECTIONS. Infections have been reported at a higher rate in patients treated with IBRANCE® plus letrozole compared to patients treated with letrozole alone in Study 1. PULMONARY EMBOLISM: Pulmonary embolism has been reported at a higher rate in patients treated with IBRANCE® plus letrozole (5%) compared with no cases in patients treated with letrozole alone in Study 1. EMBRYO-FETAL TOXICITY: Based on findings in animals and mechanism of action, IBRANCE® can cause fetal harm. **ADVERSE REACTIONS:** The most common adverse reactions are neutropenia, leukopenia, fatigue, anemia, upper respiratory infection, nausea, stomatitis, alopecia, diarrhea, thrombocytopenia, decreased appetite, vomiting, asthenia, peripheral neuropathy, and epistaxis.

API-IBRANCE-0516. Full prescribing information available upon request.

References: 1. Approved IBRANCE prescribing information LPD dated 6th May 2016. **2.** McCain J. P&T. 2015; 40(8):511-520. **3.** Finn RS, et al. *N Engl J Med*. 2016; 375(20): 1925-1936. **4.** National Comprehensive Cancer Network Breast Cancer (v2.2017) available at www.nccn.org Last accessed on 17April2017.

For Healthcare Professional Use Only.

Pfizer Oncology

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IBRANCE™ palbociclib

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TAILORED ONCOLOGY

ALL-MY-000001

KEYTRUDA®
(pembrolizumab) Injection 100 mg

KEYTRUDA®, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.[1]

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NSCLC = non-small cell lung carcinoma
EGFR = epidermal growth factor receptor
ALK = anaplastic lymphoma kinase
CI = confidence interval
HR = hazard ratio

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Combination with Chemotherapy in First-Line Metastatic Non-Squamous Non-Small Cell Lung Carcinoma[1]

Key Findings in Phase III KEYNOTE-189 Study[1]

1. In combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.[2]
2. 51% reduction in the risk of death with **KEYTRUDA® plus chemotherapy combination** vs chemotherapy combination alone (HR=0.49; 95% CI, 0.38-0.64; P<0.00001).[1]
3. Statistically significant difference in progression-free survival (PFS) with **KEYTRUDA® plus chemotherapy combination** at 8.8 months vs 4.9 months with chemotherapy combination alone (HR=0.52; 95% CI, 0.43-0.64; P<0.00001).[1]
4. 69% 1-year estimated overall survival (OS) with **KEYTRUDA® plus chemotherapy combination** vs 49% with chemotherapy combination alone.[1]
5. Statistically significant difference in objective response rate (ORR) with **KEYTRUDA® plus chemotherapy combination** at 47.6% vs 18.9% with chemotherapy combination alone (P<0.0001).[1]

Contraindications None **Precautions** Immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, nephritis, endocrinopathies and severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis. Severe infusion-related reactions have been reported. For management of immune-mediated adverse events and infusion-related reactions, see full prescribing information. **Adverse Events** Most common adverse events (reported in ≥10% of patients) with: Melanoma included arthralgia, back pain, cough, vitiligo, abdominal pain, pruritus, rash and hyponatremia. NSCLC monotherapy included cough, rash and pruritus. NSCLC combination therapy included fatigue, asthenia, diarrhea, neutropenia and rash. HNSCC, urothelial carcinoma and cHL were generally similar to those occurring in patients with melanoma or NSCLC. For detailed adverse events, please consult the full prescribing information. **Clinically Significant Drug Interactions** No metabolic drug-drug interactions are expected. Systemic corticosteroids or immunosuppressants should be avoided before starting KEYTRUDA® but they can be used after starting KEYTRUDA® to treat immune-mediated adverse reactions. Refer to the full prescribing information of KEYTRUDA® for more information. **Clinically Significant Information on Use in Specific Populations Pregnancy** There are no data on the use of pembrolizumab in pregnant women. Animal reproduction studies have not been conducted with pembrolizumab; however, blockade of PD-L1 signaling has been shown in murine models of pregnancy to disrupt tolerance to the fetus and to result in an increase in fetal loss. These results indicate a potential risk, based on its mechanism of action, that administration of KEYTRUDA® during pregnancy could cause fetal harm, including increased rates of abortion or stillbirth. KEYTRUDA® is not recommended during pregnancy unless the clinical benefit outweighs the potential risk to the fetus. Women of childbearing potential should use effective contraception during treatment with KEYTRUDA® and for at least 4 months after the last dose of KEYTRUDA®. **Nursing Mothers** It is unknown whether KEYTRUDA® is secreted in human milk. Because many drugs are secreted in human milk, a decision should be made whether to discontinue breast-feeding or to discontinue KEYTRUDA®, taking into account the benefit of breast-feeding for the child and the benefit of KEYTRUDA® therapy for the woman. **Pediatric Patients** Safety and efficacy of KEYTRUDA® in children below 18 years of age have not yet been established. **Geriatric Patients** No overall differences in safety or efficacy were reported between elderly patients (65 years and over) and younger patients (less than 65 years). No dose adjustment is necessary in this population. **Renal Impairment** No dose adjustment is needed for patients with mild or moderate renal impairment. KEYTRUDA® has not been studied in patients with severe renal impairment. **Hepatic Impairment** No dose adjustment is needed for patients with mild hepatic impairment. KEYTRUDA® has not been studied in patients with moderate or severe hepatic impairment.

References: 1. Gandhi L, Rodriguez-Abreu D, Gadgeel S, et al., for the KEYNOTE-189 Investigators. Pembrolizumab plus chemotherapy in metastatic non-small cell lung cancer. *N Engl J Med.* 2018;378(22): 2078-2092. **2.** KEYTRUDA® Local Product Circular November 2018.

MSD Oncology

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FK/MY/ONCO/0618-001

Reference: 1. XTANDI Malaysia Approved Product Insert. 2. Beer TM, Armstrong AJ, Rathkopf DE, et al., for the PREVAIL Investigators. Enzalutamide in metastatic prostate cancer before chemotherapy. N Engl J Med 2014;371(5):424-33. [Also supplementary appendix http://www.nejm.org/doi/suppl/10.1056/NEJMoa1405095/suppl_file/nejmoa1405095_appendix.pdf.]

XTANDI® (ABBREVIATED PRESCRIBING INFORMATION)

Presentation: Soft Capsules containing 40 mg of enzalutamide. **Indications:** Treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. Treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy. **Dosage:** 160 mg (four 40 mg capsules) as a single daily dose. **Method of Administration:** Xtandi is for oral use. The capsules should be swallowed whole with water, and can be taken with or without food. **Contraindication:** Hypersensitivity to the active substance or to any of the excipients. Women who are or may become pregnant. **Special Precautions:** Risk of seizure: Caution should be used in administering Xtandi to patients with a history of seizures or other predisposing factors including, but not limited to, underlying brain injury, stroke, primary brain tumours or brain metastases, or alcoholism. In addition, the risk of seizure may be increased in patients receiving concomitant medicinal products that lower the seizure threshold. The decision to continue treatment in patients who develop seizure should be taken case by case. Posterior Reversible Encephalopathy Syndrome: There have been rare reports of posterior reversible encephalopathy syndrome (PRES) in patients receiving Xtandi. PRES is a rare, reversible, neurological disorder which can present with rapidly evolving symptoms including seizure, headache, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance (MRI). Discontinuation of Xtandi in patients who develop PRES is recommended. Concomitant use with other medicinal products: Enzalutamide is a potent enzyme inducer and may lead to loss of efficacy of many commonly used medicinal products. A review of concomitant medicinal products should therefore be conducted when initiating enzalutamide treatment. Concomitant use of enzalutamide with medicinal products that are sensitive substrates of many metabolising enzymes or transporters should generally be avoided if their therapeutic effect is of large importance to the patient, and if dose adjustments cannot easily be performed based on monitoring of efficacy or plasma concentrations. Co-administration with warfarin and coumarin-like anticoagulants should be avoided. If Xtandi is co-administered with an anticoagulant metabolised by CYP2C9 (such as warfarin or acenocoumarol), additional International Normalised Ratio (INR) monitoring should be conducted. Renal impairment: Caution is required in patients with severe renal impairment as enzalutamide has not been studied in this patient population. Severe hepatic impairment: An increased drug half-life has been observed in patients with severe hepatic impairment, possibly related to increased tissue distribution. The clinical relevance of this observation remains unknown. A prolonged time to reach steady state concentrations is however anticipated, and the time to maximum pharmacological effect as well as time for onset and decline of enzyme induction may be increased. Recent cardiovascular disease: The phase 3 studies excluded patients with recent myocardial infarction (in the past 6 months) or unstable angina (in the past 3 months), New York Heart Association Class (NYHA) III or IV heart failure except if Left Ventricular Ejection Fraction (LVEF) ≥ 45%, QTcF > 470 ms bradycardia or uncontrolled hypertension. This should be taken into account if Xtandi is prescribed in these patients. Use with chemotherapy: The safety and efficacy of concomitant use of Xtandi with cytotoxic chemotherapy has not been established. Co-administration of enzalutamide has no clinically relevant effect on the pharmacokinetics of intravenous docetaxel (see section 4.5); however, an increase in the occurrence of docetaxel-induced neutropenia cannot be excluded. Excipients: Xtandi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicinal product. **Undesirable Effects:** Summary of the safety profile: The most common adverse reactions are asthenia/fatigue, hot flush, headache, and hypertension. Other important adverse reactions include falls, nonpathologic fractures, cognitive disorder, and neutropenia. Seizure occurred in 0.5% of enzalutamide-treated patients, 0.1% of placebo-treated patients, and 0.3% in bicalutamide-treated patients. Rare cases of posterior reversible encephalopathy syndrome have been reported in enzalutamide treated patients. Tabulated summary of adverse reactions: Adverse reactions observed during clinical studies are listed below by frequency category. Frequency categories are defined as follows: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. Blood and lymphatic system disorders: uncommon: leucopenia, neutropenia. General disorders: very common: asthenia/fatigue. Psychiatric disorders: common: anxiety; uncommon: visual hallucinations. Nervous system disorders: very common: headache; common: memory impairment, amnesia, disturbance in attention, restless legs syndrome; uncommon: cognitive disorder, seizure; *not known (Spontaneous reports from post-marketing experience)*: posterior reversible encephalopathy syndrome. Reproductive system and breast disorder: common: gynaecomastia. Vascular disorders: very common: hot flush, hypertension. Gastrointestinal disorders: *not known (Spontaneous reports from post-marketing experience)*: nausea, vomiting. Skin and subcutaneous tissue disorders: common: dry skin, pruritus. Musculoskeletal and connective tissue disorders: common: fractures (includes all fractures with the exception of pathological fractures); *not known (Spontaneous reports from post-marketing experience)*: myalgia, muscle spasms, muscular weakness, back pain. Description of selected adverse reactions: Seizure: In controlled clinical studies, 10 patients (0.5%) experienced a seizure out of 2051 patients treated with a daily dose of 160 mg enzalutamide, whereas one patient (< 0.1%) receiving placebo and one patient (0.3%) receiving bicalutamide, experienced a seizure. Dose appears to be an important predictor of the risk of seizure, as reflected by preclinical data, and data from a dose-escalation study. In the controlled clinical studies, patients with prior seizure or risk factors for seizure were excluded. In the AFFIRM trial, seven patients (0.9%) experienced a seizure out of 800 post-chemotherapy patients treated with a daily dose of 160 mg enzalutamide, whereas no seizures occurred in patients receiving placebo. Potentially contributing factors were present in several of these patients that may have independently increased their risk of seizure. In the PREVAIL trial, one patient (0.1%) out of 871 chemotherapy-naive patients treated with a daily dose of 160 mg enzalutamide, and one patient (0.1%) receiving placebo experienced a seizure. In bicalutamide-controlled trials, 3 patients (0.8%) out of 380 chemotherapy-naive patients treated with enzalutamide and 1 patient (0.3%) out of 387 receiving bicalutamide experienced a seizure. In a single-arm trial to assess incidence of seizure in patients with predisposing factors for seizure (where of 1.6% had a history of seizures), 8 of 366 (2.2%) patients treated with enzalutamide experienced a seizure. The median duration of treatment was 9.3 months. The mechanism by which enzalutamide may lower the seizure threshold is not known, but could be related to data from in vitro studies showing that enzalutamide and its active metabolite bind to and can inhibit the activity of the GABA-gated chloride channel. **Packs:** 112 soft capsules of 40 mg. **API date:** 15 Jan 2018.

Please refer to full prescribing information before prescribing XTANDI®. For Healthcare Professionals Only.

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*** patients with ECOG PS ≥ 2 and stable brain metastases were included**

Abbreviated Prescribing Information – GIOTRIF® (Malaysia)
Content: Afatinib dimaleate. **Indications:** As monotherapy for the treatment of Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s); locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy. **Dosage:** 40 mg once daily. **Administration:** Take at least 1 hr before or 3 hr after meals. Swallow whole. **Contraindication:** Hypersensitivity to afatinib or any of the excipients. **Special Precautions:** Assess EGFR status, diarrhoea. Patients with severe skin reactions may require temporary interruption, dose reduction & additional therapeutic intervention of therapy. Discontinue treatment if severe bullous, blistering or exfoliating conditions developed. Female gender, lower body weight & underlying renal impairment; interstitial lung disease; severe hepatic impairment; Galactose intolerance, Lapp lactase deficiency glucose-galactose malabsorption. Pregnancy & lactation. Children. **Side-effects:** Paronychia; decreased appetite; epistaxis; diarrhoea, stomatitis, nausea, vomiting; rash, dermatitis acneiform, pruritus, dry skin; cystitis; dehydration, hypokalaemia; dysgeusia; conjunctivitis, dry eye; rhinorrhoea; dyspepsia, cheilitis; increased alanine aminotransferase or aspartate aminotransferase; Palmar-plantar erythrodysaesthesia syndrome; nail disorders; muscle spasms; renal impairment/renal failure; pyrexia; decreased weight.

EM-MY-100079

[1]Hochmair M et al. Future Oncol. 2018 Oct 19; doi:10.2217/fon-2018-07

EGFR=epidermal growth factor receptor mutation positive; NSCLC=non-small cell lung cancer; TKI=tyrosine kinase inhibitor; OS=Overall Survival; ECOG PS=Eastern Cooperative Oncology Group Performance Status

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Indication[2]

Alecensa as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

Alecensa as monotherapy is indicated for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib.

References: 1. Camidge DR, Peters S, Mok T, et al. Updated efficacy and safety data from the global phase III ALEX study of alectinib (AL) versus crizotinib (CZ) in untreated advanced ALK+ NSCLC. Poster presented at: 2018 American Society of Clinical Oncology Annual Meeting; June 1-5, 2018; Chicago, IL. **2.** ALECENSA Product Insert, Malaysia. (MYAlecensa0618CDS6.0).

Basic Succinct Statement

Trade Name: Alecensa® **Active Ingredient:** Alectinib **Therapeutic Indications:** Alecensa as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). Alecensa as monotherapy is indicated for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib. **Dosage and Administration:** ALK-positive NSCLC status should be established prior to initiation of Alecensa therapy. The recommended dose of Alecensa is 600 mg (four 150 mg capsules) taken twice daily with food (total daily dose of 1200 mg). The hard capsules should be swallowed whole, and must not be opened or dissolved. Patients with underlying severe hepatic impairment (Child-Pugh C) should receive a starting dose of 450 mg taken twice daily with food (total daily dose of 900 mg). Treatment with Alecensa should be continued until disease progression or unacceptable toxicity. **Contraindications:** Hypersensitivity to alectinib or to any of the excipients. Patients with rare hereditary problems of galactose intolerance, a congenital lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Warnings and Precautions:** Monitor for interstitial lung disease (ILD)/pneumonitis. Hepatotoxicity where liver function, including ALT, AST, and total bilirubin should be monitored at baseline and then every 2 weeks during the first 3 months of treatment. Severe myalgia and creatine phosphokinase (CPK) elevation where CPK levels should be assessed every two weeks for the first month of treatment and as clinically indicated in patients reporting symptoms. Bradycardia. Photosensitivity where patients should be advised to avoid prolonged sun exposure while taking Alecensa, and for at least 7 days after discontinuation of treatment. Patients should also be advised to use a broad-spectrum Ultraviolet A (UVA)/ Ultraviolet B (UVB) sun screen and lip balm (SPF ≥50) to help protect against potential sunburn. This medicinal product contains 48 mg sodium per daily dose (1200 mg), equivalent to 2.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult. **Undesirable effects:** Anaemia, Constipation, Nausea, Diarrhoea, Vomiting, Increased bilirubin, Increased AST, Increased ALT, Rash, Myalgia, Increased blood creatine phosphokinase, Oedema, Weight Increased. **Pregnancy and Lactation:** Alecensa may cause foetal harm when administered to a pregnant woman. Studies in animals have shown reproductive toxicity. Female patients, who become pregnant while taking Alecensa or during the 3 months following the last dose of Alecensa must contact their doctor and should be advised of the potential harm to the foetus. It is unknown whether alectinib and its metabolites are excreted in human milk. A risk to the newborn/infant cannot be excluded. Mothers should be advised against breast-feeding while receiving Alecensa. **Packaging:** Multipack of 224 (4 packs of 56) hard capsules. Each hard capsule contains: Alectinib 150 mg (equivalent to 161.3 mg alectinib hydrochloride). Full details on composition, indications, contraindications, side effects, dosage and precautions are available upon request MYAlecensa0618CDS6.0).

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alectinib 150 mg capsules

HOW TO GET THERE

If you drive a car, you may park in the public parking area in the university or UMMC. Kindly note that we are unable to reserve a parking space for participants.

If you travel by train, the nearest LRT station is the Universiti Station. You may take a bus (RAPID bus No.780 or 790) to reach UM. It will stop at the front of PJ main gate along Jalan Universiti. The auditorium is located within the Faculty of Medicine.

If you travel by GRAB, please select “Faculty of Medicine – UM” as drop off point.

Venue

TJ Danaraj Auditorium, Faculty of Medicine, University Malaya (UM)