MSCT

Masterclass in Systemic Cancer Therapy

featuring Immuno-oncology

Malaysian Oncological Society

UNIVERSITY OF MALAYA

Date : 9th - 10th March 2018
Venue : TJ Danaraj Auditorium, Universiti Malaya, Faculty of Medicine
Email : register.msct2018@gmail.com (For Registration)
enquiry.msct2018@gmail.com (For Enquiry)

(CME points will be awarded)

Roche

For patients with HER2-positive metastatic breast cancer

"TOGETHER, WE RAISE the survival standard"[1-3]

PERJETA-Herceptin combination: setting the new standard of survival for first-line treatment of HER2-positive mBC[1-3]

Trastuzumab provides significant clinical benefit to patients with mBC. However, some patients still experience disease progression[1,4]

- **Time to disease progression in HER2-positive patients has increased with the development of different therapy combinations with HER2-targeted agents[1]**
- **Despite this, approximately 50% of patients with mBC progress within 12 months of first-line trastuzumab treatment, with progressively worse outcomes in second or later lines, highlighting the need to do more[1,5]**

References: 1.Marty M, Cognetti F, Maraninchi D, et al. Randomized phase II trial of the efficacy and safety of trastuzumab combined with docetaxel in patients with human epidermal growth factor receptor 2–positive metastatic breast cancer administered as first-line treatment: the M77001 Study Group. J Clin Oncol. 2005;23:4265-4274. 2. Baselga J, Cortés J, Kim S-B, et al; CLEOPATRA Study Group. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med. 2012;366:109-119. 3. Valero V, Forbes J, Pegram MD, et al. Multicenter phase III randomized trial comparing docetaxel and trastuzumab with docetaxel, carboplatin, and trastuzumab as first-line chemotherapy for patients with HER2-gene-amplified metastatic breast cancer (BCIRG 007 Study): two highly active therapeutic regimens. J Clin Oncol. 2011;29:149-156. 4. Slamon DJ, Leyland-Jones B, Shak S, et al. Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2. N Engl J Med.2001;344:783-792. 5. . Slamon D, Leyland-Jones B, Shak S et al. Use of Chemotherapy plus a Monoclonal Antibody against HER2 for Metastatic Breast Cancer That Overexpresses HER2. New England Journal of Medicine. 2001;344(11):783-792. doi:10.1056/nejm200103153441101.

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PERJETA® pertuzumab Herceptin® trastuzumab

Message from Head of Department,

Clinical Oncology Unversity of Malaya Medical Centre

I would like to personally welcome each of you to the Masterclass in Systemic Cancer Therapy (MSCT) 2018. This is the second 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 2018 is enriched further with a selection of new topics and special feature on immune-oncology. 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.

Dr Rozita Abdul Malik

Organizing Committee

1. Wan Zamaniah Wan Ishak (Chairperson)
2. Adlinda Alip
3. Amirah Remlee@Ramli
4. Carolyn Eng Chai Hui
5. Chan Renn-Syin
6. Chan Ming Jun
7. Christpine Menti Sarie
8. Erica Lee Chai Young
9. Jasmin Munchar Elias
10. Marniza Saad
11. Ooi Po Lin
12. Patricia Shamani
13. Syafirin Ab Sani
14. Vance Koi Yung Chean

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2. Anita Zarina Bustam
3. Ho Gwo Fuang
4. Marniza Saad
5. Mastura Md Yusof
6. Rozita Abdul Malik
7. Wan Zamaniah Wan Ishak
8. Jasmin Loh Pei Yuin

Faculty List

1. Anita Zarina Bustam
2. Bee Ping Chong
3. Carolyn Eng Chai Hui
4. Flora Chong Li Tze
5. Fuad Ismail
6. Gan Gin Gin
7. Harissa Husainy Hasbullah
8. Ho Gwo Fuang
9. Ibtisam Mohd Noor
10. Jennifer Leong Siew Mooi
11. Junie Khoo Yu Yen
12. Marfu'ah Nik Eezamuddeen
13. Mastura Md Yusof
14. Mukhri Hamdan
15. Muhammad Azrif Ahmad Annuar
16. Muthukkumaran Thiagarajan
17. Ros Suzanna Bustamam
18. Rosszai Ibrahim
19. Soo Hoo Hwoei Fen
20. Suhana Yusak
21. Tan Chia Jie
22. Tan Wen Chieh
23. Tho Lye Mun
24. Toh Han Chong
25. Vaishnavi Jeyasingam
26. Wong Yoke Fui
27. Yoong Boon Koon

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. **SPs** Arterial thromboembolic events, gastrointestinal perforations, severe bleeding, pulmonary 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.

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MYCYR2018/02/002

Lilly

[a]mPC = metastatic adenocarcinoma of the pancreas; [b]NSCLC = non-small cell lung cancer; [c]mBC = metastatic breast cancer

Reference: Abraxane Product Information.

Refer to the full Prescribing Information before prescribing. Full Prescribing Information is available on request.
Name of medicine: Abraxane for Injectable Suspension 100mg. **Active ingredients:** paclitaxel formulated as albumin bound nanoparticles. **List of excipients:** Human albumin solution (containing sodium, sodium caprylate and N-acetyl DL tryptophanate). **Dosage form:** Powder for suspension for infusion. **Indication(s).** Abraxane monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated. In combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. In combination with carboplatin is indicated as first-line treatment of locally advanced or metastatic non-small cell lung cancer, in patients who are not candidates for curative surgery or radiation therapy. **Dosage regimens and routes of administration:** Breast Cancer - 260 mg/m^2 administered intravenously over 30 minutes every 3 weeks. Pancreatic adenocarcinoma - 125 mg/m^2 administered intravenously over 30 minutes on Days 1, 8 and 15 of each 28-day cycle in combination with gemcitabine. Non-Small Cell Lung Cancer –100 mg/m^2 administered as an intravenous infusion over 30 minutes on Day 1, 8 and 15 of each 21-day cycle in combination of Carboplatin. Administer reconstituted Abraxane suspension intravenously using an infusion set incorporating a 15 µm filter. **Reference to special groups of patients:** Patients with severe hepatic impairment should not be treated with paclitaxel. Insufficient data are currently available to recommend dose modifications in patients with renal impairment or mild to moderate hepatic impairment. The safety and efficacy of Abraxane in children and adolescents aged 0-17 years has not been established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Lactation. Patients who have baseline neutrophil counts < 1500 cells/mm^3. **Warnings:** Abraxane should not be substituted for or with other paclitaxel formulations. It is an albumin-bound nanoparticle formulation of paclitaxel, which may have substantially different pharmacological properties compared to other formulations of paclitaxel. Bone marrow suppression (primarily neutropenia) and Sensory neuropathy occur frequently with Abraxane. Refer to the full prescribing information for dose adjustments and interruptions during treatment in the case of haematologic (neutropenia and/ or thrombocytopenia) and peripheral neuropathy. The toxicity of paclitaxel can be increased with hepatic impairment, administration in patients should be performed with caution. Patients receiving Abraxane should be vigilantly monitored for the occurrence of cardiac events. If patients experience nausea, vomiting and diarrhoea following the administration of Abraxane, they may be treated with commonly used anti emetics and constipating agents. Carefully assess patients with pancreatic adenocarcinoma aged 75 years and older for their ability to tolerate Abraxane in combination with gemcitabine. Give special consideration to performance status, co-morbidities and increased risk of infections. Prescribers should consult the full Prescribing Information for other warnings. **Clinically significant interactions:** In the absence of a PK drug-drug interaction study, caution should be exercised when administering paclitaxel concomitantly with medicines known to inhibit or induce either CYP2C8 or CYP3A4. **Commonly reported side effects:** Neutropenia, peripheral neuropathy, arthralgia/ myalgia and gastrointestinal disorders. Prescribers should consult the full Prescribing Information for other side-effects. **Date of last revision:** 24/5/2016

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AS_2017_016

Masterclass in Systemic Cancer Therapy (MSCT) 2018

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

Date : 9th - 10th March 2018
Venue : TJ Danaraj Auditorium, Faculty of Medicine, UM

MSCT2018 is the second event following the successful inaugural event last year. The agenda for MSCT2018 is enriched further with a selection of new topics and special feature on immuno-oncology.

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

Halaven®
(eribulin mesilate) Injection

Indication

Metastatic Breast Cancer

HALAVEN® 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. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

LENVIMA®
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Indication

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Agenda

Day 1 : Friday 9th March 2018

Introductory Session

Chairperson : **Marniza Saad**

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

Plenary 1

Chairperson : **Adlinda Alip**

08:25 - 08:45	**Assessment of response to systemic cancer therapy**	**Marfu'ah Nik Eezamuddeen** Clinical Oncologist, Universiti Teknologi MARA
08:45 - 09:05	**Analgesics for cancer pain** Supported by Mundi Pharma	**Vaishnavi Jeyasingam** Clinical Oncologist, Hospital Kuala Lumpur
09:05 - 09:25	**Alkylating agents**	**Suhana Yusak** Clinical Oncologist, Institut Kanser Negara
09:25 - 09:45	**Platinum agents**	**Jennifer Leong Siew Mooi** Clinical Oncologist, Institut Kanser Negara
09:45 - 10:05	**Antimetabolites**	**Anita Bustam** Clinical Oncologist, Universiti Malaya Medical Centre
10:05 - 10:35	**Anti-ALK therapy** TEA Symposium Supported by Pfizer	**Junie Khoo Yu Yen** Clinical Oncologist, Hospital Umum Sarawak
10:35 - 10:45	**Q&A**	**All Speakers**

Plenary 2

Chairperson : **Rozita Abdul Malik**

10:45 - 11:05	**Antimicrotubules** Supported by Eisai	**Carolyn Eng Chai Hui** Pharmacist, Universiti Malaya Medical Centre
11:05 - 11:25	**Topoisomerase inhibitors**	**Tan Wen Chieh** Pharmacist, Universiti Malaya Medical Centre
11:25 - 11:45	**Miscellaneous cytotoxic drugs**	**Muthukkumaran Thiagarajan** Clinical Oncologist, Hospital Kuala Lumpur
11:45 - 12:05	**Mechanism of drug resistance**	**Wong Yoke Fui** Clinical Oncologist, Institut Kanser Negara
12:05 - 12:25	**Chemotherapy-induced nausea and vomiting** Supported by MSD	**Tan Chia Jie** Pharmacist, National University Singapore
12:25 - 12:35	**Q&A**	**All Speakers**
12:35 - 13:20	**Opening of Plenary 3 featuring Immuno-Oncology and Immunotherapeutic strategies** LUNCH Symposium Supported by MSD	**Toh Han Chong** Medical Oncologist, National Cancer Centre Singapore
13:20 - 14:30	**BREAK**	

Plenary 3

Chairperson : **Wan Zamaniah**

14:30 - 15:00	**Immune-checkpoint inhibitors** Supported by Roche	**Toh Han Chong** Medical Oncologist, National Cancer Centre Singapore
15:00 - 15:30	**Immune-mediated toxicities** Supported by Roche	**Tan Chia Jie** Pharmacist, National University Singapore
15:30 - 16:00	**Combining immunotherapy with other cancer treatment**	**Tho Lye Mun** Clinical Oncologist, Sunway Medical Centre
16:00 - 16:30	**Biomarkers in immunotherapy** TEA Symposium Supported by MSD	**Tho Lye Mun** Clinical Oncologist, Sunway Medical Centre
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 : Saturday **10th March** 2018

Plenary 4

Chairperson : **Syafirin Ab Sani**

08:15 - 08:45	**VEGF-targeted therapy** Supported by Eli Lilly	**Flora Chong Li Tze** Clinical Oncologist, Hospital Likas Sabah
08:45 - 09:15	**EGF-targeted therapy** Supported by Amgen	**Junie Khoo Yu Yen** Clinical Oncologist, Hospital Umum Sarawak
09:15 - 09:35	**Anti-CDK4/6 therapy** Supported by Pfizer	**Ho Gwo Fuang** Clinical Oncologist, Universiti Malaya Medical Centre
09:35 - 09:55	**Somatostatin targeted therapy** Supported by Novartis	**Wong Yoke Fui** Clinical Oncologist, Institut Kanser Negara
09:55 - 10:25	**Bone targeting agents** TEA Symposium Supported by Amgen	**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	**The drug development of systemic cancer therapy** Supported by Frasenius Kabi	**Fuad Ismail** Clinical Oncologist, Univ. Keb. Malaysia Medical Centre
11:05 - 11:25	**The pharmacological aspect** Supported by CCM	**Fuad Ismail** Clinical Oncologist, Univ. Keb. Malaysia Medical Centre
11:25 - 11:45	**Tailoring treatment in special situations**	**Harissa Husainy Hasbullah** Clinical Oncologist, Universiti Teknologi MARA
11:45 - 12:05	**Chemotherapy and pregnancy**	**Mastura Md Yusof** Clinical Oncologist, Pantai Hospital Kuala Lumpur
12:05 - 12:25	**Biomarkers & relevance to clinical practice**	**Mastura Md Yusof** Clinical Oncologist, Pantai Hospital Kuala Lumpur
12:25 - 12:35	**Q&A**	**All Speakers**
12:35 - 12:45	**Quiz**	
12:45 - 13:30	**HER2-targeted therapy** LUNCH Symposium Supported by Roche	**Soo Hoo Hwoei Fen** Clinical Oncologist, Hospital Pulau Pinang
13:30 - 14:00	**BREAK**	

Plenary 6

Chairperson : **Patricia Shamani**

14:00 - 14:20	**Acute & late toxicity and grading**	**Ros Suzanna Ahmad Bustamam** Clinical Oncologist, Hospital Kuala Lumpur
14:20 - 14:40	**Granulocyte colony stimulating factors** Supported by Sanofi	**Ibtisam Mohd Nor** Clinical Oncologist, Hospital Kuala Lumpur
14:40 - 15:00	**Effects of systemic therapy on liver prior to surgery**	**Yoong Boon Koon** Hepatobiliary Surgeon, Universiti Malaya Medical Centre
15:00 - 15:10	**Q&A**	**All Speakers**

Agenda

Day 2 : Saturday **10th March** 2018

Plenary 7 Chairperson : **Marniza Saad**

15:10 - 15:30	**High dose chemotherapy**	**Gan Gin Gin** Haemato-Oncologist, Universiti Malaya Medical Centre
15:30 - 15:50	**Fertility issues and fertility sparing options**	**Mukhri Hamdan** Gynaecologist, Universiti Malaya Medical Centre
15:50 - 16:10	**Anti-coagulation – Guide for oncologists**	**Bee Ping Chong** Haemato-Oncologist, Universiti Malaya Medical Centre
16:10 - 16:30	**Extravasation**	**Rosszai Ibrahim** Oncology Sister, Universiti Malaya Medical Centre
16:30 - 17:00	**Endocrine therapy** TEA Symposium Supported by Astellas	**Muhammad Azrif Ahmad Annuar** Clinical Oncologist, Prince Court Medical Centre
17:00 - 17:10	**Q&A**	**All Speakers**
17:10 - 17:30	**PRIZES & CLOSING**	

***Prizes will be awarded to all quiz winners**

Vectibix® panitumumab | TARGETED PERSONALISED MEDICINE.

STEP TOWARDS VICTORY WITH VECTIBIX®

1st line treatment in combination with FOLFOX for your wild-type RAS mCRC patients[1,2]

- EARLY TUMOR SHRINKAGE[1,2]
- PROGRESSION-FREE SURVIVAL[1,2]
- OVERALL SURVIVAL[1,2]

mCRC = metastatic colorectal cancer

Vectibix – Abbreviated PI

Indications: Treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC) (see full PI PRECAUTIONS – Laboratory tests): as first-line therapy in combination with FOLFOX.; as second-line therapy in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan). As monotherapy in patients after the failure of of fluoropyrimidine-, oxaliplatin-, and irinotecan- containing chemotherapy regimens. **Contraindications:** history of life-threatening hypersensitivity reactions to panitumumab or any product component. For patients with mutant RAS mCRC or for whom RAS status is unknown, the combination of Vectibix with oxaliplatin-based chemotherapy is contraindicated (see full PI WARNINGS AND PRECAUTIONS). **Precautions:** Assess risk-benefit prior to initiation in patients with ECOG 2 performance status. Monitor dermatologic reactions and soft tissue toxicity (severe or life-threatening reactions – discontinue or withhold dose). Patients should wear sunscreen and a hat and limit sun exposure. Severe infusion reactions – Vectibix should be permanently discontinued. Hypersensitivity reactions. Acute onset/worsening pulmonary toxicity – interrupt therapy and investigate symptoms. Avoid combination with IFL chemotherapy or bevacizumab-containing chemotherapy. Acute renal failure has been observed in patients who develop severe diarrhoea and dehydration. Monitor for keratitis or ulcerative keratitis. Monitor for hypomagnesaemia and hypocalcaemia prior, during and 8 weeks after therapy – replete electrolytes as appropriate. Determine KRAS and NRAS mutational status using a validated test in an experienced laboratory (see full PI RAS Tumour Genetic Marker testing). **Pregnancy:** Vectibix has the potential to cause foetal harm when administered to pregnant women. May impair fertility in women. Caution: no breast-feeding during and for 2 months after the last dose of Vectibix. Paediatric safety and efficacy not established. **Adverse Reactions:** Skin reactions occurring in 93% of patients. Commonly reported adverse reactions were gastrointestinal disorders [diarrhoea (50%), nausea (41%), vomiting (27%), constipation (23%) and abdominal pain (23%)]; general disorders [fatigue (37%), pyrexia (20%)]; metabolism and nutrition disorders [anorexia (27%)]; infections and infestations [paronychia (20%)]; and skin and subcutaneous disorders [rash (45%), dermatitis acneiform (39%), pruritus (35%), erythema (30%) and dry skin (22%)]. **Dosage and Administration:** 6 mg/kg by IV infusion once every 2 weeks until disease progression.

AMGEN internal reference : 150716MY_Vectibix

References: 1. Douillard JY, et al. Impact of early tumour shrinkage and resection on outcomes in patients with wild-type RAS metastatic colorectal cancer. Eur J Cancer 2015;51:1231-1242. **2.** Rivera F, et al. Final analysis of the randomised PEAK trial: overall survival and tumour responses during first-line treatment with mFOLFOX6 plus either panitumumab or bevacizumab in patients with metastatic colorectal carcinoma. Int J Colorectal Dis 2017; DOI 10.1007/s00384-017-2800-1 (epublished 19 April).

For Medical/Healthcare Professionals Only

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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]

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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.

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Speaker's Profile

Anita Zarina Bustam, Prof Dr

Consultant Clinical Oncologist, Clinical Oncology Department, Universiti Malaya Medical Centre

Dr Anita Bustam is an academic clinician in the field of Clinical Oncology at the University of Malaya Medical Centre. She underwent both undergraduate (1986-1992) and post graduate (1995-1999) training in Wales, United Kingdom. She was the Head of Clinical Oncology Unit, Faculty of Medicine University of Malaya from the year 2000 to 2013. Her research activities include conducting Phase 2 and 3 clinical trials on various common tumour sites, supervising and co-supervising postgraduate students' project in clinical as well as pre-clinical areas. Of recent years her clinical work mostly focuses on breast, lung, paediatric and brain cancers. Together with her colleagues from the Ministry of Health in Malaysia and Universiti Kebangsaan Malaysia, she has been very involved in the training of future oncologists in Malaysia. She is currently a committee and writing group member of the national curriculum for Clinical Oncology training programme in Malaysia.

Bee Ping Chong, Assoc Prof Dr

Consultant Hematologist, Medical department, Faculty of Medicine, University of Malaya.

Assoc 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 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, Ms

Pharmacist, University of 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. Currently practicing under Inpatient Pharmacy Chemotherapy (IPC) which provides clinical pharmacy services to the Oncology and Haematology units of UMMC.

Flora Chong Li Tze, Dr

Clinical Oncologist, Radiotherapy and Oncology Department,
Likas Hospital, Kota Kinabalu, Sabah.

Dr. Flora Chong Li Tze is a Clinical Oncologist at the Radiotherapy and Oncology Department of Hospital Wanita dan Kanak-Kanak Sabah (HWKKS), Kota Kinabalu. She obtained her Bachelor of Medicine and Surgery from the University of Auckland, New Zealand in 2001. She received post-graduate training in Clinical Oncology at University Malaya from 2007 to 2011. She worked as a specialist at Hospital Kuala Lumpur from June 2011 to March 2012 before moving back to her home state in Sabah. Her areas of interest include breast cancer, colorectal and upper gastrointestinal cancers, as well as urological tumours and radiotherapy in paediatric cancers. She is also involved in clinical trials for the various tumour sites.

Fuad Bin Ismail, Prof Dato' Dr

Consultant Clinical Oncologist, Radiotherapy & Oncology, Pusat Perubatan Universiti Kebangsaan Malaysia 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 UKMMC 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.

Gan Gin Gin, Prof Dr

Consultant Hematologist, Department of Medicine, Faculty of Medicine, University Malaya Medical Centre

Dr Gan Gin Gin obtained his medical degree from University Of New South Wales, Australia and completed her FRCP and MRCP at Royal College of Physicians, United Kingdom. She has been trained in Clinical haematology since 1999. Her special interests are mainly in lymphoma and transplantation. She is previously secretary of Malaysian Society of Haematology (MSH) and now a current council member of MSH.

Harissa Husainy Hasbullah, Dr

Clinical Oncologist, Universiti Teknologi MARA

Dr Harissa obtained her MbCHB from Glasgow Medical School. Subsequently upon returning to Malaysia, she joined UiTM as a trainee lecturer before embraking into oncology master programme in UM. She obtained her specialist qualification in Master Clinical Oncology (UM) in 2014. Since then she has been practicing in General Hospital Kuala Lumpur as a clinical oncologist whilst oversee some lecturing role in UiTM Medical Faculty. She is also interested in and is actively involved in Industry Sponsored Research in HKL.

Ho Gwo Fuang, Assoc Prof Dr

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

Dr Ho is an associate professor and consultant in clinical oncology at University Malaya Medical Centre and University Malaya specialist Centre, Kuala Lumpur. He was trained at Barts and The London NHS Trust and The Royal Marsden NHS Trust in London. He attained Certificate for Completion of Specialist Training (CCST) in 2007 and joined the Faculty of Medicine at University Malaya. He was the recipient of Joint Commission Internatinal (JCI) Outstanding Young Malaysian Award in 2009 for medical innovation. His research interests involve breast, gastrointestinal and gynaecological cancers. He is involved in many national and international collaborative research work and is a council member of Malaysian Oncological Society (MOS).

Jennifer Leong Siew Mooi, Dr

Clinical Oncologist, Department of Radiotherapy & Oncology National Cancer Institute (IKN)

Dr Jennifer Leong Siew Mooi is a practicing clinical oncologist at Institut Kanser Negara. Dr Jennifer received her undergraduate training and medical degree from International Medical University and trained as a houseman at Hospital Pulau Pinang. She went on to jointhe Respiratory Department as a medical officer where she developed an interest in oncology and cancer care. Having pursued her interest in oncology further, Dr Jennifer graduated with Masters in Clinical Oncology from University Malaya in 2015. She is a member of the Malaysian Oncological Society and European Society of Medical Oncology. Dr Jennifer is also currently involved in the update of the clinical practice guideline for management of breast cancer.

Junie Khoo Yu Yen, Dr

Clinical Oncologist, Clinical Oncology Department
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.

Ibtisam Muhamad Nor, Dr

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.

Mastura Md Yusof, Dr

Consultant Clinical Oncologist,
Pantai Hospital Kuala Lumpur,
Sime Darby Medical Center

Beginning her year in oncology since 2000, Dr Mastura obtained her Master in Clinical Oncology from Universiti Malaya in 2009. She left her Associate Professor and Consultant Clinical Oncologist post at University Malaya in 2015 to begin private practice at Pantai Hospital Kuala Lumpur and Sime Darby Medical Centre. Her clinical and research interest covers various cancer types, including breast, colorectal and lung. A council member of the Malaysian Oncological Society, a member of international cancer organizations and several NGOs, she has participated in multiple clinical trials, advisory boards, expert committee panels and has authored articles in peer-reviewed medical journals.

Muhammad Azrif, Dr

Consultant Clinical Oncologist,
Prince Court Medical Centre

Dr Azrif trained at the Christie Hospital, UK, from 2000 to 2006 and did his one year fellowship in Radiation Oncology in Toronto. He was previously at Universiti Kebangsaan Malaysia Medical Center from 2007 to 2012.

Mukhri Hamdan, Dr

Associate Professor and Consultant of Obstetrics and Gynaecology, Subspecialist in Infertility and Reproductive Medicine/Surgery, University of Malaya Medical Centre

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.

Muthukkumaran Thiagarajan, Dr

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.

Ros Suzanna Ahmad Bustamam, Dr

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

Dr Ros Suzanna is the Head of Department, Department of Radiotherapy and Oncology, Hospital Kuala Lumpur. She completed her Master in Clinical Oncology, UM in 2010. The tumour sites of her interest are breast, gynaecology and head and neck cancers. She was in the Working Group for Cervical Cancer CPG 2016 and Systemic Therapy Protocol 2017. She serves as principal investigator for clinical research in colorectal, breast and prostate cancers in HKL.

Suhana Yusak, Dr

Clinical Oncologist, Department of Radiotherapy & Oncology National Cancer Institute (IKN)

Dr Suhana obtained her MBBS degree from University of Malaya in 2002 and completed her training is Masters of Clinical Oncology in 2012. She is currently practicing in National Cancer Institute, Putrajaya.

Toh Han Chong, Dr

Senior Consultant and Deputy Director, National Cancer Centre Singapore (NCCS)

Dr Toh Han Chong is Senior Consultant and Deputy Director, National Cancer Centre Singapore (NCCS). He is Associate Professor at the Cancer & Stem Cell Biology Program, Duke-NUS, and adjunct Principal Investigator, Institute of Molecular and Cell Biology, A*STAR. Dr Toh graduated from the University of London, UK, with an Intercalated Bachelor of Science in 'Infection and Immunity' from St Mary's Hospital Medical School and qualified as a medical doctor from University of Cambridge, UK. Dr Toh obtained his Fellowship of the Royal College of Physicians in 2003. He received his medical oncology fellowship training at the Singapore General Hospital, Massachusetts General Hospital, Harvard Medical School, Boston, USA and at the Center for Cell and Gene Therapy, Baylor College of Medicine, Houston, Texas, USA. Dr Toh was past Chairman of the Chapter of Medical Oncology, College of Physicians, and past President of the Singapore Society of Oncology. He was previously Editor of the Singapore Medical Association News for 14 years. Dr Toh is a recipient of the National Senior Clinician Scientist Award 2017 for his translational work in the biology and translational research in liver cancer. Dr Toh is co-leading PI for an international randomized phase III trial of adjuvant aspirin in resected colorectal cancer that is nearly completed, and coordinating PI for the world's first FDA Phase III randomized clinical trial of T cell therapy for cancer. Dr Toh and his team have been pioneers of cancer immunotherapy and cell therapy in Singapore and the region for over 15 years. Dr Toh has published over 100 peer review journal papers to date. He has delivered numerous plenary lectures internationally including the Humanitas Lecture at Instituto Clinico Humanitas in Milan Italy, and The Oda Memorial Lecture at the National Centre for Global Health and Medicine in Tokyo, Japan, both in 2017.

Tan Wen Chieh, Mr

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.

Tho Lye Mun, Dr

Consultant Clinical Oncologist, Sunway Medical Centre

Dr Tho Lye Mun graduated from University of Sydney, Australia in 1998. He obtained his MRCP and FRCR in the UK. He then pursued a PhD in molecular oncology at the University of Glasgow as a Cancer Research UK Fellow, completing in 2011. He has an interest in immunotherapy and radiosurgery and has been PI for several clinical trials. He serves as treasurer of Malaysian Oncologial Society and Vice President of South East Asian Radiation Oncology Group (SEAROG).

Vaishnavi Jeyasingam, Dr

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.

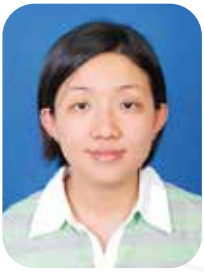
Tan Chia Jie, Mr

Graduate Student, Department of Pharmacy, National University of Singapore

Practised in Hospital Sultanah Aminah, Johor Bahru until 2017. Was involved in oncology/hematology services and cytotoxic drug reconstitution. Obtained board certification in oncology pharmacy from Board of Pharmacy Specialties in 2016. Currently pursuing PhD in National University of Singapore. Research interests include supportive care in cancer.

Wong Yoke Fui, Dr

Clinical Oncologist, National Cancer Institute



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.

Yoong Boon Koon, Assoc Prof

Consultant Hepatobiliary Surgeon, Hepatobiliary Team, Surgical Department, UMMC

Associate Professor Yoong Boon Koon qualified his BSc(med) and MBBS degree in University of New South Wales (Aust) in 1996 and completed his Master of Surgery in University of Malaya in 2006. He further pursued his Hepatopancreaticobiliary(HPB) Surgery and Liver Transplantation training in Queen Mary Hospital under the mentorship of Prof ST Fan and Prof CM Lo in 2009. Upon return, he re-established the University Malaya Medical Center Hepatobiliary unit in 2010 and started the first Living Donor Liver Transplantation in University Malaya Medical Center in 2017. His main interest is in complex HPB surgery and liver transplantation, including laparoscopic HPB surgery. His interest is also in researches and currently involved in internationally collaborated researches. He is currently a Consultant Hepatobiliary Surgeon and the Head of Hepatobiliary Unit of University Malaya Medical Centre.

Soo Hoo Hwoei Fen, Dr

Clinical Oncologist, Hospital Pulau Pinang

Dr Soo Hoo completed her FRCR training in The Christie NHS Foundation Trust, Manchester, in October 2014. Since then she has been working as a clinical oncologist in Hospital Kuala Lumpur. She is involved with the National Curriculum Writing Group for Clinical Oncology and continuous medical education for junior doctors in Hospital Kuala Lumpur. 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.

Rosszai @ Rozi Ibrahim, SRN

Oncology Head Nurse, University of Malaya Medical Centre

Rosszai @ Rozi Ibrahim is now the Head Nurse at Clinical Oncology & Medical Daycare, University Malaya Medical Centre. Her academic qualifications include BNSc (Clinical) and Oncology Care Nursing Cert, RN. She previously served in Medical Ward from 1989-1993, Adult Bone Marrow Transplant from 1993-2004 and Hemato-Oncology Day Care 2006-2009.

Marfu’ah Nik Eezamuddeen, Dr

Clinical Oncologist and Lecturer, Faculty of Medicine, University Teknologi Mara

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.

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References
1. Kim JM and Sung MK. The efficacy of oral nutritional intervention in malnourished cancer patients: a systemic review. Clin Nutr Res 2016; 5(4): 219-236.
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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. 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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 (whereof 1.6% had a history of seizures), 8 of 366 (2.2%) patients treated with enzalutamide experienced a seizure. 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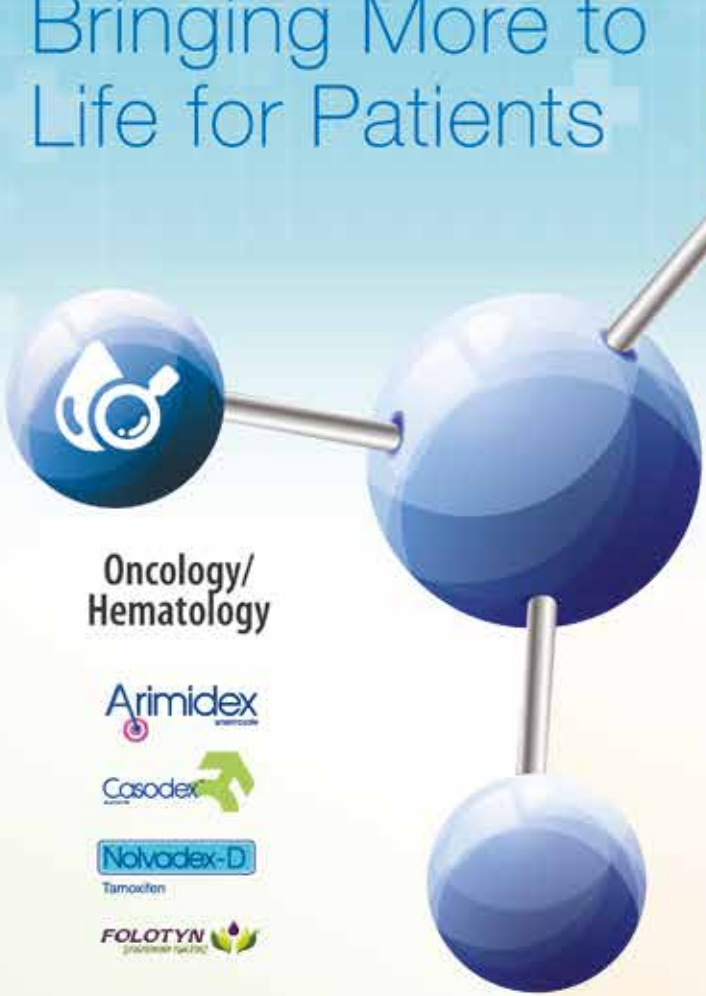

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Prevalence on NET type[3]	sst_1	sst_2	sst_3	sst_4	sst_5
Carcinoid	76%	80%	43%	68%	77%
Gastrinoma	79%	93%	36%	61%	93%
Insulinoma	76%	81%	38%	58%	57%
Nonfunctioning islet cell tumour	58%	88%	42%	48%	50%
Inhibitory effect[1,4]:					
Hormone secretion	+	+			+
Proliferation	+	+	+		+
Induction of apoptosis		+	+		

ENETS 2016 Guidelines[5]

- For antiproliferative purposes, Somatostatin Analogue (SSA) may be used in stable or progressive disease or in patients with unknown tumour behaviour
- SSA is recommended as 1st-line therapy in midgut NET
- SSA can be considered in low-grade NET (G1/G2) of other sites (rectal, bronchial NET) when SSTR+, preferably with Ki-67 <10%

SANDOSTATIN® LAR® is indicated for[6]

- Treatment of patients with advanced neuroendocrine tumors of the midgut or unknown primary origin where non-midgut sites of origin have been excluded.
- Treatment of patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumors in whom symptoms are adequately controlled on s.c. treatment with Sandostatin: carcinoid tumours with features of the carcinoid syndrome, VIPomas, glucagonomas, gastrinomas/Zollinger-Ellison syndrome, insulinomas, GRFomas.

Basic Prescription Information

Important note: Before prescribing, consult full prescribing information. **Presentations:** Kit with vial adapter and safety needle: Octreotide acetate. Vials containing 10 mg, 20 mg or 30 mg octreotide free peptide supplied as powder (microspheres) for suspension for injection together with a prefilled syringe (solvent for parenteral use), containing: sodium carboxymethylcellulose (14 mg), mannitol (72 mg), polysorbate 188 (4 mg), water for injection qs ad 2 mL; vial adapter; one safety needle. **Indication:** •Treatment of patients with Acromegaly: who are adequately controlled on s.c. treatment with Sandostatin; in whom surgery or radiotherapy is inappropriate or ineffective; or in the interim period until radiotherapy becomes fully effective. •Treatment of patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumors in whom symptoms are adequately controlled on s.c. treatment with Sandostatin: carcinoid tumors with features of the carcinoid syndrome, VIPomas, glucagonomas, gastrinomas/Zollinger-Ellison syndrome, insulinomas, GRFomas. •Treatment of patients with advanced neuroendocrine tumors of the midgut or unknown primary origin where non-midgut sites of origin have been excluded. **Dosage:** 10 to 40 mg every 4 weeks, administered as a deep intragluteal injection. **Contraindications:** Known hypersensitivity to octreotide or to any of the excipients. **Warnings/Precautions:** •Dose adjustments of drugs such as antidiabetics, beta-blockers, calcium channel blockers, or agents to control fluid and electrolyte balance, may be necessary; •Caution in patients with insulinomas. •Caution in patients with diabetes mellitus. •Thyroid function should be monitored in patients receiving prolonged treatment with octreotide. •Periodic examination of gallbladder. •Monitoring of vitamin B12 levels in patients who have a history of vitamin B12 deprivation. •Caution in pregnant women; patients should be advised to use adequate contraception if necessary. •Patients should not breast-feed during Sandostatin LAR treatment. **Interactions:** •Impaired intestinal absorption of ciclosporin, cimetidine; increased bioavailability of bromocriptine. •Caution with concomitant use of drugs mainly metabolised by CYP3A4 and which have a low therapeutic index. •Dose adjustments of drugs such as antidiabetics, beta-blockers, calcium channel blockers, or agents to control fluid and electrolyte balance, may be necessary. **Adverse reactions:** •Very common (≥1/10) adverse drug reactions are: diarrhea, abdominal pain, nausea, constipation, flatulence, headache, cholelithiasis, hyperglycemia, and injection-site reaction. •Common (≥1/100, <1/10) adverse drug reactions are: dyspepsia, vomiting, abdominal bloating, steatorrhea, loose stools, discoloration of faeces, dizziness, asthenia, hypothyroidism, thyroid dysfunction (e.g. decreased thyroid stimulating hormone [TSH], decreased Total T4, and decreased Free T4), cholecystitis, biliary sludge, hyperbilirubinemia, hypoglycemia, impairment of glucose tolerance, anorexia, elevated transaminase levels, pruritus, rash, alopecia, dysphea, and bradycardia. •Uncommon (≥1/1000, <1/100) adverse drug reactions are: dehydration, and tachycardia. •Post-marketing the following adverse reactions have been reported: anaphylaxis, allergy/hypersensitivity reactions, urticaria, acute pancreatitis, acute hepatitis without cholestasis, cholestatic hepatitis, cholestasis, jaundice, cholestatic jaundice, arrhythmia, increased alkaline phosphatase levels, and increased gamma glutamyl transferase levels. **Packs and prices:** Country specific. **Legal classification:** Country specific. BSS SANDOSTATIN LAR RD 3 MAY 16;APPR 29 AUG 17

References: 1. Rinke A, Müller H-H, Schade-Brittinger C, et al. Placebo-controlled, double-blind, prospective, randomized study on the effect of octreotide LAR in the control of tumor growth in patients with metastatic neuroendocrine midgut tumors: a report from the PROMID Study Group. J Clin Oncol. 2009;27:4656-4663. **2.** Hofland LJ. J Endocrinol Invest. 2003;26 (8 suppl):8-13. **3.** Ferrante E, Pellegrini C, Bondioni S, et al. Endocr Relat Cancer. 2006; 13:955-962. **4.** Susini C, Buscail L.Ann Oncol. 2006;17:1733-1742. **5.** Pavel M et al. Neuroendocrinology 2016;103:172-185. **6.** Sandostatin LAR PI RD 03 MAY 16;APPR 29 AUG 17.

For Healthcare Professionals only. Full prescribing information available from:

NOVARTIS

Novartis Corporation (Malaysia) Sdn Bhd (10920H)
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A first-in-class CDK4/6 inhibitor for postmenopausal women with ER+ HER2- metastatic breast cancer.[1,2]

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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.

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Pfizer Oncology

Pfizer (Malaysia) Sdn Bhd (40131-T)
Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur.
Telephone : 03-2281 6000 Fax : 03-2281 6388

IBRANCE™ palbociclib

PP-IBR-MYS-0003 - 26OCT2017

[a]ALK status determined by validated ALK tests

Xalkori® Abbreviated Product Information[13]

Xalkori® (crizotinib) capsules, oral. **PRESENTATION:** Crizotinib 200 mg and 250mg hard gelatin capsule. **INDICATIONS AND USAGE:** Crizotinib is indicated for the treatment of advanced non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive. **DOSAGE AND ADMINISTRATION:** The recommended dose of crizotinib is 250 mg orally, twice daily. **CONTRAINDICATIONS:** Hypersensitivity to crizotinib or to any of the excipients. **WARNINGS AND PRECAUTIONS:** PREGNANCY: Women of childbearing potential should be advised of the potential hazard to the fetus and to avoid becoming pregnant. QT INTERVAL PROLONGATION: Prolonged QT intervals have been observed. Avoid use in patients with congenital long QT syndrome. When using crizotinib, monitoring with on-treatment electrocardiograms and electrolytes should be considered. CARDIAC FAILURE: Severe, life-threatening, or fatal adverse reactions of cardiac failure were reported. Patients with or without pre-existing cardiac disorders, receiving crizotinib, should be monitored for signs and symptoms of heart failure BRADYCARDIA: Symptomatic bradycardia can occur. Avoid using crizotinib in combination with other agents known to cause bradycardia. Monitor heart rate and blood pressure regularly. SEVERE VISUAL LOSS: Grade 4 visual field defect with vision loss occurred. Optic atrophy and optic nerve disorder have been reported as potential causes of vision loss. HEPATOTOXICITY: Drug-induced hepatotoxicities with fatal outcomes have occurred. Monitor liver function test including ALT, AST and total bilirubin every 2 weeks during the first 2 months of treatment, then once a month and as clinically indicated, with more frequent repeat testing for increased liver transaminases, alkaline phosphatase, or total bilirubin in patients who developed transaminase elevations. PNEUMONITIS: Crizotinib has been associated with severe, life-threatening, or fatal treatment related pneumonitis in clinical trials. Permanently discontinue crizotinib in patients diagnosed with treatment- related pneumonitis. **ADVERSE REACTIONS:** The most common and common adverse reactions of crizotinib (≥5% for any grade and ≥2% for grade 3 & 4) are electrocardiogram QT prolonged, bradycardia, vision disorder, vomiting, nausea, diarrhea, constipation, dyspepsia, dysphagia, abdominal pain, esophagitis, edema, pyrexia, upper respiratory infection, increased weight, pain in extremity, muscle spasm, dizziness, dysgeusia, headache, syncope, fatigue, decreased appetite, decreased weight, neuropathy, rash, renal cyst, dyspnea, pulmonary embolism, elevated transaminases, neutropenia, lymphopenia, hypokalemia and hypophosphatemia.

API-XALKORI-0517

Full prescribing information available upon request.

Reference: Xalkori Approved Malaysia Prescribing Information LPD dated 29 May 2017.

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Pfizer Oncology

Pfizer (Malaysia) Sdn Bhd (Company No: 40131-T)
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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/CDS33.0)

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In patients whose tumors express PD-L1[1,2,3]

GIVE YOUR PATIENTS A KEY TO **SUPERIOR OVERALL SURVIVAL**

1st-LINE
treatment in metastatic NSCLC vs platinum-containing chemotherapy[2]

2nd-LINE
or greater treatment in advanced NSCLC vs docetaxel[3]

KEYTRUDA® (pembrolizumab) is indicated for the first-line treatment of patients with metastatic non–small cell lung carcinoma (NSCLC) whose tumors express PD-L1 with a ≥50% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations.

KEYTRUDA® is indicated for the treatment of patients with advanced NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA®.

PD-L1 = programmed death ligand 1; EGFR = epidermal growth factor receptor; ALK = anaplastic lymphoma kinase.

References:
1. KEYTRUDA® pack insert March 2017. **2.** Reck M, Rodríguez-Abreu D, Robinson AG, *et al.* Pembrolizumab versus chemotherapy for PD-L1–positive non–small-cell lung cancer. *N Engl J Med.* 2016;375(19):1823–1833. **3.** Herbst RS, Baas P, Kim D-W, *et al.* Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. *Lancet.* 2016;387(10027):1540–1550.

Selected Safety Information

CONTRAINDICATIONS: KEYTRUDA® is contraindicated in patients with hypersensitivity to pembrolizumab or any of the inactive ingredients. **PRECAUTIONS/ WARNINGS:** •Immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, nephritis, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, For management of immune-mediated adverse events and infusion-related reactions, see full prescribing information. **ADVERSE EVENTS:** •Most common adverse reactions (reported in ≥10% of patients) with: Melanoma included arthralgia, back pain, cough, vitiligo, abdominal pain, pruritus, rash, hyponatremia. NSCLC included cough, rash, pruritus. HNSCC 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 immunosuppressant should be avoided before starting KEYTRUDA® treatment, but they can be used after starting KEYTRUDA® to treat immune-mediated adverse reactions. Refer to the local 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. •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: Safety and efficacy of KEYTRUDA® in children below 18 years of age have not yet been established. •Geriatric population: 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. **INDICATIONS:** •Melanoma: KEYTRUDA® (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma. •Non-Small Cell Lung Carcinoma: KEYTRUDA® is indicated for the first-line treatment of patients with metastatic non-small cell lung carcinoma (NSCLC) whose tumors express PD-L1 with a ≥50% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. KEYTRUDA® is indicated for the treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have disease progression on or after platinum- containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving KEYTRUDA®. •Head and Neck Cancer: KEYTRUDA® is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. This indication is approved based on the overall response rate (ORR) and durability of response. Continued approval for this indication may be contingent upon the verification of the results from the confirmatory clinical studies. **DOSING:** •KEYTRUDA® is administered as an intravenous infusion over 30 minutes every 3 weeks. •The recommended dose of KEYTRUDA® is: •200 mg for head and neck cancer or previously untreated NSCLC. •2 mg/kg for melanoma or previously treated NSCLC. Patients should be treated with KEYTRUDA® until disease progression or unacceptable toxicity.

Before prescribing KEYTRUDA®, please read the accompanying Prescribing Information.

MSD Oncology

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HOW TO GET THERE

If you drive a car, you may park in the public parking area in the university. 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 TJ Danaraj Library at Faculty Medicine.

Venue

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