MSCT

MASTERCLASS IN SYSTEMIC CANCER THERAPY 2021

Cancer Therapeutics: Back to Basics, Forward to the Future

Session 1: Chemotherapy and Hormonal Therapy
(4 - 5 September 2021; 0800H - 1600H)

Session 2: Targeted therapy
(11 - 12 September 2021; 0800H - 1600H)

Email: msctummc2021@gmail.com (for inquiries)

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MASTERCLASS IN SYSTEMIC CANCER THERAPY (MSCT) 2021 AGENDA

DAY 1 - 4TH SEPTEMBER 2021 (SATURDAY)

Time	Topics	Speakers
0900	Welcome address	
Plenary 1: Moderator Dr Mariam		
0905-0930	Drug development: From discovery to clinical application *Supported by Fresenius Kabi*	Fuad Ismail Clinical Oncologist, UKM Medical Centre
0930-1000	The pharmacological aspect of cytotoxics	Fuad Ismail Clinical Oncologist, UKM Medical Centre
1000-1015	Q&A	
1015-1030	BREAK	
Plenary 2: Moderator Dr Lau Ron Hsien		
1030-1100	Antimetabolites	Khairiyah Sidek Clinical Oncologist, UKM Medical Centre
1100-1130	Topoisomerase Inhibitors	Nur Ain binti Rosli Ahmad Abdullah Pharmacist, Hospital Tengku Ampuan Rahimah Klang
1130-1200	Platinum agents	Loong Ly Sia Pharmacist, UKM Medical Centre
1200-1215	Q&A	
1215-1230	BREAK	
Plenary 3: Moderator Dr Zulaikha Rozman		
1230-1300	Antimicrotubules *Supported by Eisai*	Carolyn Eng Chai Hui Pharmacist, University Malaya Medical Centre
1300-1330	Alkylating agents	Kamarun Neasa Begam binti Mohd Kassim Pharmacist, Institut Kanser Negara
1330-1400	Response assessment of systemic cancer therapy	Mohamad Nazri bin Md Shah Radiologist, University Malaya Medical Centre
1400-1415	Q&A	
1415-1430	Closing	

MASTERCLASS IN SYSTEMIC CANCER THERAPY (MSCT) 2021 AGENDA

DAY 2 - 5TH SEPTEMBER 2021 (SUNDAY)

Time	Topics	Speakers
Plenary 4: Moderator Dr Nurul Iman Fathi		
0900-0930	Acute and late toxicity of systemic treatment	Muthukkumaran Thiagarajan Clinical Oncologist, Hospital Kuala Lumpur
0930-1000	Antiemetics	Nahjatul Abdul Ghafar Clinical Oncologist, Hospital Likas Sabah
1000-1030	Analgesics for cancer pain	Vaishnavi Jeyasingam Clinical Oncologist, Hospital Kuala Lumpur
1030-1045	Q&A	
1045-1100	BREAK	
Plenary 5: Moderator Dr Esther Kang		
1100-1130	Endocrine therapy in Male Cancers *Supported by Astellas*	Ravindran Kanesvaran Medical Oncologist, NCCS Singapore
1130-1200	Endocrine therapy in Female Cancers *Supported by Dr Reddy*	Marfu'ah Nik Eezamuddeen Clinical Oncologist, HUKM
1200-1230	Tailoring treatment in special situations	David Lee Clinical Oncologist, Hospital Likas Sabah
1230-1245	Q&A	
1245-1300	BREAK	
Plenary 6: Moderator Dr Noor Nabila		
1300-1330	Mechanism of drug resistance	Rozita binti Abdul Malik Clinical Oncologist, University Malaya Medical Centre
1330-1400	Chemotherapy and pregnancy	Mastura Md Yusof Clinical Oncologist, Pantai Hospital Kuala Lumpur
1400-1425	Fertility issues and fertility sparing options	Mukhri Hamdan Gynaecologist, University Malaya Medical Centre
1425-1450	Management of Systemic Therapy in the Covid Era	Nur Fadhlina Abdul Satar Clinical Oncologist, University Malaya Medical Centre
1450-1505	Q&A	
1505-1530	QUIZ (plenary 1-6), winners and close	

MASTERCLASS IN SYSTEMIC CANCER THERAPY (MSCT) 2021 AGENDA

DAY 3 - 11TH SEPTEMBER 2021 (SATURDAY)

Time	Topics	Speakers
Plenary 1: Moderator Dr Yong Chen Joyce		
0900-0905	Welcome address	
0905-0930	Personalized medicine in cancer therapeutics: past, present and future *Supported by Merck*	Ho Kean Fatt Clinical Oncologist, Mt Miriam Cancer Hospital
0930-1000	Biomarkers and Cancer Genomic Profiling *Supported by AstraZeneca*	Mastura Md Yusof Clinical Oncologist, Pantai Hospital Kuala Lumpur
1000-1015	Q&A	
1015-1030	BREAK	
Plenary 2: Moderator Dr Nur Faizah Muin		
1030-1100	EGFR-targeted therapy *Supported by Boehringer Ingelheim*	Sumitra Thongprasert Medical Oncologist, Bangkok Hospital Chiang Mai
1100-1130	ALK/ROS-1 Inhibitor Therapy *Supported by Roche*	Junie Khoo Yu Yen Clinical Oncologist, Beacon Hospital
1130-1200	Multikinase Inhibitors I *Supported by Eisai*	Tan Chih Kiang Clinical Oncologist, Tung Shin Hospital
1200-1215	Q&A	
1215-1230	BREAK	
Plenary 3: Moderator Dr Cheong E Von		
1230-1300	BRAF/MEK inhibitors	John Low Clinical Oncologist, Pantai Hospital Kuala Lumpur
1300-1330	HER-2 targeted therapy *Supported by Roche*	Doris Chow Clinical Oncologist, Mt Miriam Cancer Hospital
1330-1400	CDK4/6, PIK3CAi, AKT and mTOR inhibitors *Supported by Pfizer*	Senthil Rajappa Medical Oncologist, Hyderabad India
1400-1415	Q&A *Supported by Zuellig Pharma*	
1415-1430	Closing	

MASTERCLASS IN SYSTEMIC CANCER THERAPY (MSCT) 2021 AGENDA

DAY 4 - 12TH SEPTEMBER 2021 (SUNDAY)

Time	Topics	Speakers
Plenary 4: Moderator Dr Rangasamy Ramachandran		
0900-0930	Somatostatin targeted therapy *Supported by Ipsen*	David Tai Medical Oncologist, NCCS Singapore
0930-1000	PARP inhibitors	Rebecca Dent Medical Oncologist, NCCS Singapore
1000-1030	Immune - checkpoint inhibitors *Supported by Roche*	Toh Han Chong Medical Oncologist, NCCS Singapore
1030-1100	VEGF Targeted Therapy and Multikinase inhibitors II *Supported by Ipsen*	Syadwa Abdul Shukor Clinical Oncologist, Hospital Umum Sarawak
1100-1115	Q&A	
1115-1130	BREAK	
Plenary 5: Moderator Dr Vickee Rajeswaran		
1130-1200	Biosimilar : Development and challenges *Supported by Duopharma*	Chua Hui Ming Pharmacist, National Pharmaceutical Regulatory Agency
1200-1230	Immune-mediated toxicities	Ibtisam Muhamad Nor Clinical Oncologist, Hospital Kuala Lumpur
1230-1300	Other rarer mutations/targets and intervention	Wan Zamaniah Wan Ishak Clinical Oncologist, University Malaya Medical Centre
1300-1315	Q&A	
1315-1330	BREAK	
Plenary 6: Moderator Dr Edmund Chin		
1330-1400	CAR T cell therapy	Gan Gin Gin Haematologist, University Malaya Medical Centre
1400-1430	High dose chemotherapy *Supported by BD*	Bee Ping Chong Haematologist, University Malaya Medical Centre
1430-1455	Extravasation	Suzila Bt Sulaiman, Oncology Nurse, University Malaya Medical Centre
1455-1510	Q&A	
1510-1530	QUIZ (plenary 7-12), winners and closing	

ORGANIZING COMMITTEE

1. Dr. Nisha Mohd Shariff (Chairperson)
2. Dr. Mariam Zafirah
3. Dr. Noor Nabila
4. Ms. Yok Yong
5. Dr. Cheong E Von
6. Dr. Yong Chen Joyce
7. Dr. Zulaikha Rozman
8. Dr. Rangasamy
9. Ms. Christpine Menti Sarie
10. Dr. Nurul Iman

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3. Prof. Adlinda Alip
4. Prof. Marniza Saad
5. Prof. Rozita Malik
6. Prof. Wan Zamaniah
7. Dr. Nur Fadhlina
8. Dr. Nisha Shariff

INTERNATIONAL SPEAKERS

PROF EMERITUS DR SUMITRA THONGPRASERT

Consultant Medical Oncologist
Bangkok Hospital Chaing Mai

ASSOCIATE PROF DR RAVINDRANKANESVARAN

Consultant Medical Oncologist
National Cancer Centre Singapore

ASSOCIATE PROF DR REBECCA DENT

Consultant Medical Oncologist
National Cancer Centre Singapore

DR SENTHIL RAJAPPA

Consultant Medical Oncologist
Hyderabad, India

CLINICAL ASSISTANT PROF DR DAVID TAI

Consultant Medical Oncologist
National Cancer Centre Singapore

ASSOCIATE PROF DR TOH HAN CHONG

Consultant Medical Oncologist
National Cancer Centre Singapore

NATIONAL SPEAKERS

ASSOCIATE PROF DR MOHAMAD NAZRI BIN MD SHAH
Consultant Clinical Radiologist, Nuclear Medicine Physician
University Malaya Medical Centre

DR MUTHUKKUMARAN THIAGARAJAN
Consultant Clinical Oncologist
Hospital Kuala Lumpur

DR NAJATUL ADBUL GHAFAR
Consultant Clinical Oncologist
Hospital Kuala Lumpur

DR VAISHNAVI JEYASINGAM
Consultant Clincal Oncologist
Hospital Kuala Lumpur

DR NUR FADHLINA ABDUL SATAR
Consultant Clinical Oncologist
University Malaya Medical Centre

DR HO KEAN FATT
Consultant Clinical Oncologist
Mount Miriam Cancer Hospital

NATIONAL SPEAKERS

PROF DATO' DR FUAD ISMAIL
Consultant Clinical Oncologist
Hospital Canselor Tuanku Mukhriz UKM

ASSOCIATE PROF DR ROZITA MALIK
Consultant Clinical Oncologist
University Malaya Medical Centre

PROF DR GAN SHIAW SZE@GAN GIN GIN
Consultant Clinical Haematologist
University Malaya Medical Centre

DR TAN CHIH KIANG
Consultant Clincal Oncologist
Tung Shin Hospital,
Thompson Hospital

DR JUNIE KHOO YU YEN
Consultant Clinical Oncologist
Beacon Hospital

DR DAVID LEE
Clinical Oncologist
Sabah Women & Children Hospital

NATIONAL SPEAKERS

DR MASTURA MD YUSOF

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

ASSOCIATE PROF DR WAN ZAMANIAH WAN ISHAK

Consultant Clinical Oncologist
University Malaya Medical Centre

PROF DR BEE PING CHONG

Consultant Clinical Haematologist
University Malaya Medical Centre

ASSOCIATE PROF DR MUKHRI HAMDAN

Consultant in Obstetrics & Gynaecology
University Malaya Medical Centre

DR JOHN LOW

Consultant Clinical Oncologist
Pantai Hospital Kuala Lumpur,
Sunway Medical Centre

DR DORIS CHOW

Consultant Clinical Oncologist
Mount Miriam Cancer Hospital,
Pantai Hospital Penang

NATIONAL SPEAKERS

DR MARFU'AH NIK EEZAMUDDEEN
Consultant Clinical Oncologist
Hospital Canselor Tuanku Mukhriz UKM

DR SYADWA ABDUL SHUKOR
Clinical Oncologist
Sarawak General Hospital

DR IBTISAM MUHAMAD NOR
Consultant Clinical Oncologist
Hospital Kuala Lumpur

DR KHAIRIYAH SIDEK
Clinical Oncologist
Hospital Canselor Tuanku Mukhriz UKM

CAROLYN ENG CHAI HUI
Pharmacist
University Malaya Medical Centre

CHUA HUI MING
Pharmacist
National Pharmaceutical Regulatory Agency (NPRA)

NATIONAL SPEAKERS

LOONG LY SIA
Pharmacist
Hospital Canselor Tuanku Mukhriz UKM

KAMARUN NEASA BEGAM BINTI MOHD KASSIM
Pharmacist
National Cancer Institute, Malaysia

SUZILA BINTI SULAIMAN
Oncology Nurse
University Malaya Medical Centre

NUR AIN BINTI ROSLI AHMAD ABDULLAH
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THE GOAL IS CURE

FURTHER REDUCE HER RISK IN EARLY HER2+ BREAST CANCER[2,3]

PERJETA® pertuzumab
Herceptin® trastuzumab
DUAL HER2 BLOCKADE. PROVEN SYNERGY.

1. Tecentriq Malaysia Pack Insert, MYTecentriq20201218CDS25.0
2. Perjeta Malaysia Pack Insert, MYPerjeta20210215CDS12.0
3. Cheng YC, Ueno NT. Improvement of survival and prospect of cure in patients with metastatic breast cancer. Breast Cancer. 2011;19(3):191-199. doi:10.1007/s12282-011-0276-3.

Basic Succinct Statement

Trade Name: Tecentriq® ,**Active Ingredient:** Atezolizumab **Therapeutic Indications: Non-Small Cell Lung Cancer (NSCLC) (i) 1L NSCLC with high PD-L1 expression:** Tecentriq, as a single agent, is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), with no EGFR or ALK genomic tumor aberrations. Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test. **(ii) 1L Non-Squamous NSCLC in combination with Avastin:** Tecentriq, in combination with Avastin, paclitaxel and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations. **(iii) 1L Non-Squamous NSCLC in combination with chemotherapy:** Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumour aberrations. **(iv) 2L NSCLC:** Tecentriq is indicated for the treatment of patients with metastatic NSCLC 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. **Extensive-Stage Small Cell Lung Cancer (ES-SCLC):** Tecentriq is indicated for the first-line treatment of patients with ES-SCLC in combination with carboplatin and etoposide. **Triple Negative Breast Cancer (TNBC):** Tecentriq in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic TNBC whose tumours have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease. **Hepatocellular carcinoma (HCC):** Tecentriq, in combination with Avastin, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. **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. Do not co-administer other medicinal products through the same infusion line. Substitution by any other biological medicinal product requires the consent of the prescribing physician. 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. **(i) Tecentriq as a single agent:** *NSCLC* - The recommended dose of Tecentriq is either: 1) 840 mg administered by IV infusion every 2 weeks, or 2) 1200 mg administered by IV infusion every three 3 weeks, or. 3) 1680 mg administered by IV infusion every 4 weeks. **(ii) Tecentriq combination therapy:** *1L Non-Squamous NSCLC in combination with Avastin* - Induction phase: The recommended dose of Tecentriq is 1200 mg administered by intravenous (IV) infusion, followed by Avastin, paclitaxel, and then carboplatin every 3 weeks for four or six cycles. The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq followed by Avastin, is administered by IV infusion every 3 weeks. Refer to the Prescribing Information for the chemotherapy agents administered in combination with Tecentriq for recommended dosing information. 1L Non-Squamous NSCLC in combination *with nab-paclitaxel and carboplatin* - Induction phase, the recommended dose of Tecentriq is 1200 mg administered by intravenous (IV) infusion, followed by nab-paclitaxel and carboplatin every 3 weeks for four or six cycles. For each 21-day cycle, Tecentriq, nab-paclitaxel and carboplatin is administered on day 1. In addition, nab-paclitaxel is administered on days 8 and 15. The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq is administered by IV infusion every 3 weeks. ES-SCLC – Induction phase: The recommended dosage of Tecentriq is 1200 mg intravenously followed by carboplatin, and then etoposide administered by IV infusion on day 1. Etoposide is also administered by IV infusion on days 2 and 3. This regimen is administered every 3 weeks for four cycles. Maintenance Phase: Following completion of 4 cycles of carboplatin and etoposide, the recommended dosage of Tecentriq is 1200 mg by IV infusion every 3 weeks until loss of clinical benefit or unacceptable toxicity. TNBC - The recommended dose of Tecentriq is 840mg administered by IV infusion, followed by 100mg/m2 nab-paclitaxel. For each 28-day cycle, Tecentriq is administered on days 1, and 15 while nab-paclitaxel is administered on days 1, 8 and 15. Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test. Patients are treated with Tecentriq until disease progression or unacceptable toxicity.*HCC* - Administer Tecentriq 1200 mg intravenously followed by Avastin on the same day every 3 weeks. If Avastin is discontinued, administer Tecentriq as 840 mg every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks. **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, nephritis, myositis, severe cutaneous adverse reaction). **Undesirable effects:** Tecentriq Monotherapy - Diarrhea, Nausea, Vomiting, Fatigue, Asthenia, Pyrexia, Urinary tract infection, decreased appetite, Arthralgia, Back Pain, Musculoskeletal Pain, Headache, Cough, Dyspnea, Rash, Pruritus *Tecentriq Combination Therapy* - Anemia, Neutropenia, Thrombocytopenia, Leukopenia, Hypothyroidism, Constipation,Oedema Peripheral, Lung Infection, Peripheral neuropathy, Nasopharyngitis,Alopecia, Hypertension. **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. Female patients of childbearing potential should use highly effective contraception and take active measures to avoid pregnancy while undergoing Tecentriq treatment and for at least 5 months after the last dose. **Packaging:** Single-use vials containing preservative-free, colorless to slightly yellow solution, at an active ingredient concentration of 60mg/mL, as follows, 14 mL vial containing a total of 840 mg atezolizumab and 20 mL vial containing a total of 1200 mg atezolizumab. Full details on composition, indications, contraindications, side effects, dosage and precautions are available upon request (MYTecentriq20201218CDS25.0, DCA 353 - 5 Feb 2021, DCA 354 - 2 March 2021).

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. Perjeta and Herceptin should be administered sequentially and can be given in any order. When administered with Perjeta, the recommendation is to follow a 3-weekly schedule for Herceptin either as an IV infusion with an initial dose of 8 mg/kg followed every 3 weeks thereafter by a dose of 6 mg/kg body weight or a fixed dose of Herceptin subcutaneous (SC) injection (600mg) for the initial dose and every 3 weeks thereafter irrespective of the patient's body weight. 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 (MYPerjeta20210215CDS12.0).

• Perjeta should be avoided during pregnancy unless the potential benefit for the mother outweighs the potential risk to the foetus. There are no studies of Perjeta in pregnant women and the safe use of Perjeta during pregnancy and lactation has not been established)• Verify pregnancy status prior to the initiation of PERJETA. Women of child bearing potential should use effective contraception while receiving Perjeta and for 6 months following the last dose of Perjeta.• Monitor patients who become pregnant during PERJETA therapy or within 6 months following the last dose of PERJETA closely for oligohydramnios.• If PERJETA is used during pregnancy or if a patient becomes pregnant while being treated with PERJETA or within 6 months following the last dose of PERJETA, immediately report exposure to the local Roche Adverse Event Line at (Tel) +603-76285600 or through email at my.drugsafety@roche.com.• Additional information will be requested during a PERJETA-exposed pregnancy and the first year of the infant's life. This will enable Roche/Genentech to better understand the safety of PERJETA and to provide appropriate information to Health Authorities, Healthcare Providers and patients.

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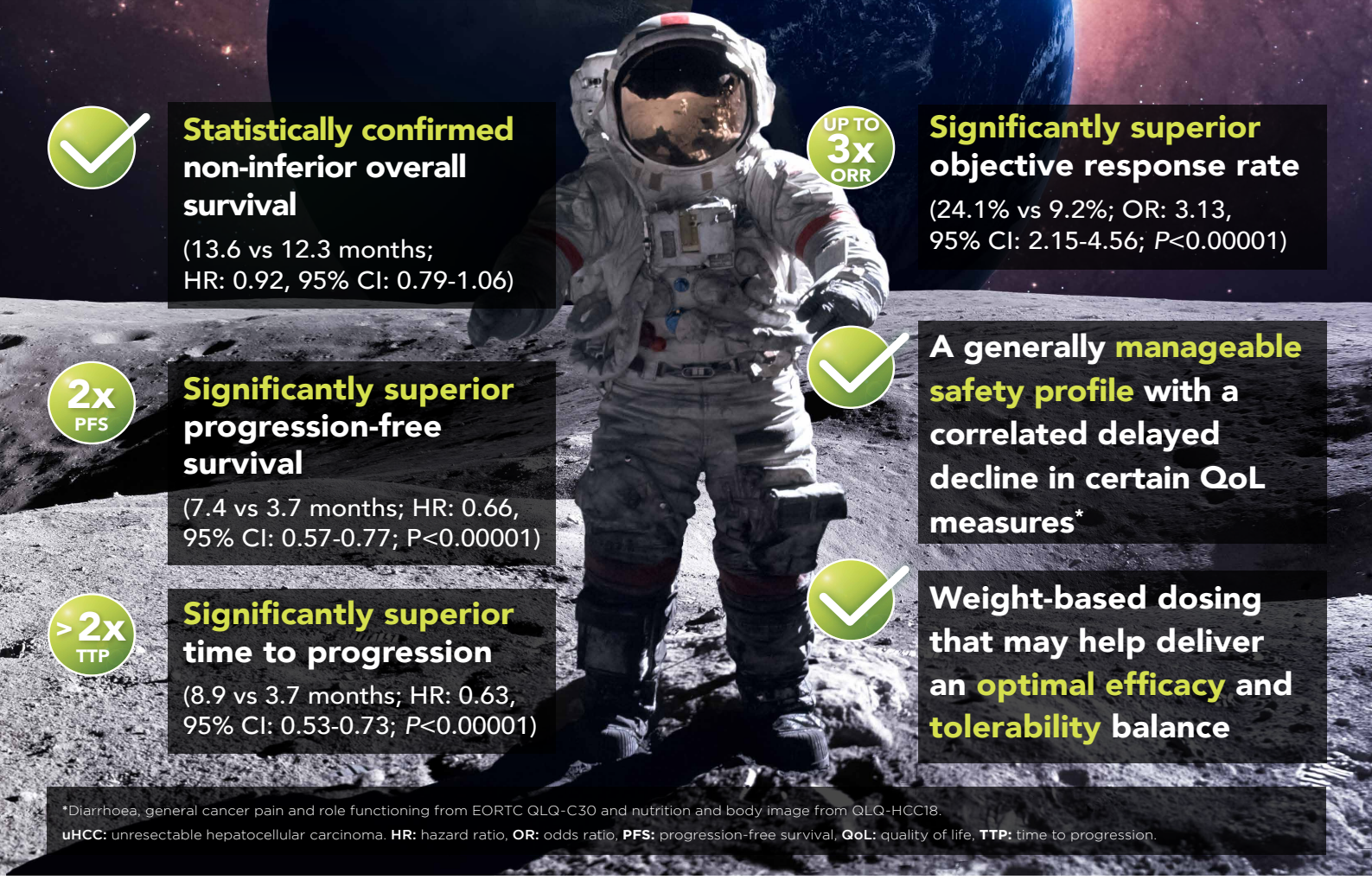
LENVIMA® is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.[1]

In a large, global phase 3 first-line study vs sorafenib, LENVIMA® has met the primary endpoint:[2]



Statistically confirmed non-inferior overall survival

(13.6 vs 12.3 months; HR: 0.92, 95% CI: 0.79-1.06)

UP TO 3x ORR

Significantly superior objective response rate

(24.1% vs 9.2%; OR: 3.13, 95% CI: 2.15-4.56; *P*<0.00001)

2x PFS

Significantly superior progression-free survival

(7.4 vs 3.7 months; HR: 0.66, 95% CI: 0.57-0.77; P<0.00001)

A generally manageable safety profile with a correlated delayed decline in certain QoL measures*

>2x TTP

Significantly superior time to progression

(8.9 vs 3.7 months; HR: 0.63, 95% CI: 0.53-0.73; *P*<0.00001)

Weight-based dosing that may help deliver an optimal efficacy and tolerability balance

*Diarrhoea, general cancer pain and role functioning from EORTC QLQ-C30 and nutrition and body image from QLQ-HCC18.

uHCC: unresectable hepatocellular carcinoma. **HR:** hazard ratio, **OR:** odds ratio, **PFS:** progression-free survival, **QoL:** quality of life, **TTP:** time to progression.

PRESCRIBING INFORMATION

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 PDGFR, 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. •LENVIMA® is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy. • Lenvima, in combination with Pembrolizumab, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who has disease progression following prior platinum-based systemic therapy and are not candidates for curative surgery or radiation. **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. HCC - The recommended daily dose of lenvatinib is 8 mg (two 4 mg capsules) once daily for patients with a body weight of < 60 kg and 12 mg (three 4 mg capsules) once daily for patients with a body weight of ≥ 60 kg. Dose adjustments are based only on toxicities observed and not on body weight changes during treatment. The daily dose is to be modified, as needed, according to the dose/toxicity management plan. EC - The recommended dosage of LENVIMA® is 20 mg orally once daily, in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks, until unacceptable toxicity or disease progression. **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 30ºC. **Date of Revision of PI:** Jun 2020.

References: 1. LENVIMA® SmPC. **2.** Eisai Data on file 2017. Dose modification table.

For healthcare professional only.
Full prescribing information available on request.

Eisai (Malaysia) Sdn. Bhd. (18039-D)
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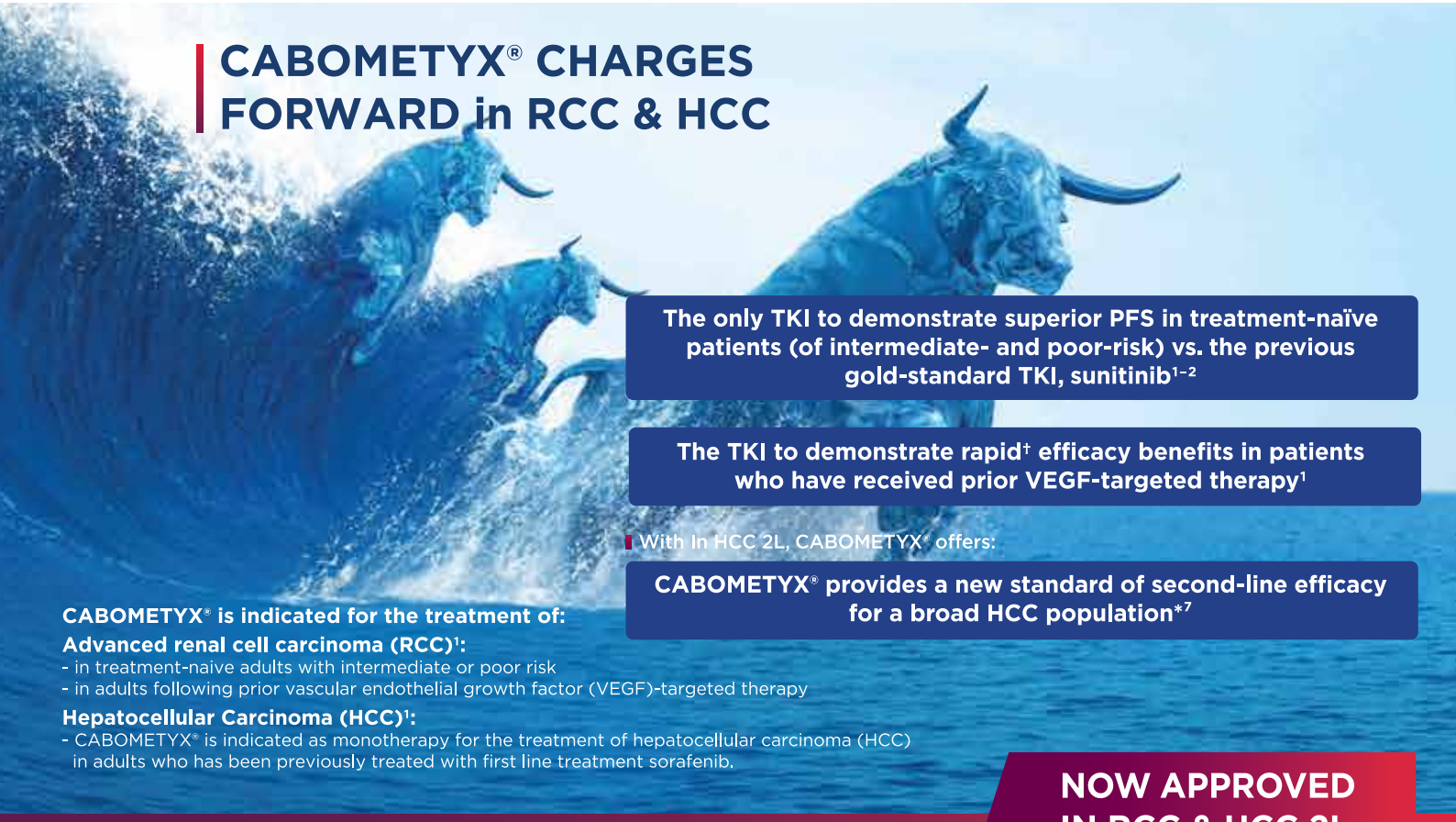
LENVIMA® (lenvatinib) capsules | RESPONSE THAT MATTERS

CABOMETYX®
(cabozantinib) tablets
60 mg | 40 mg | 20 mg



CABOMETYX® CHARGES FORWARD in RCC & HCC

The only TKI to demonstrate superior PFS in treatment-naïve patients (of intermediate- and poor-risk) vs. the previous gold-standard TKI, sunitinib[1–2]

The TKI to demonstrate rapid† efficacy benefits in patients who have received prior VEGF-targeted therapy[1]

With In HCC 2L, CABOMETYX® offers:

CABOMETYX® provides a new standard of second-line efficacy for a broad HCC population*[7]

CABOMETYX® is indicated for the treatment of:

Advanced renal cell carcinoma (RCC)[1]:
- in treatment-naive adults with intermediate or poor risk
- in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy

Hepatocellular Carcinoma (HCC)[1]:
- CABOMETYX® is indicated as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who has been previously treated with first line treatment sorafenib.

NOW APPROVED IN RCC & HCC 2L

Make your choice count with CABOMETYX®

Superior efficacy in aRCC[1–3]
After prior
VEGF-targeted therapy[1,2]
(Superiority over everolimus)

Treatment-naïve patients[3]
(Superiority over sunitinib)

Efficacy in a broad ITT patient population in HCC 2L[7]

Manageable tolerability[3,7]

Validated by major international bodies and guidelines **(NCCN, ESMO and EMA)**
4-6, 8-10

†Median time-to-response of 1.9 months ‡11 *Broad range of patients including those with portal/MVI, EHS, sorafenib intolerance and HCV/HBV
AFP: Alpha Fetoprotein; ECOG: Eastern Cooperative Oncology Group, EHS: Extrahepatic Spread, HBV: Hepatitis B Virus, HCC: Hepatocellular Carcinoma, HCV: Hepatitis C Virus, MVI: Macrovascular Invasion, TKI: Tyrosine kinase inhibitors, VEGF: Vascular endothelial growth factor

References
1. Choueiri TK, Escudier B, Powles T, et al. Cabozantinib versus everolimus in advanced renal-cell carcinoma (METEOR): final results from a randomised, open-label, phase 3 trial. Lancet Oncol. 2016; 17(7): 917-927. 2. Motzer RJ, Escudier B, Powles T, et al. Long-term follow-up of overall survival for cabozantinib versus everolimus in advanced renal cell carcinoma. Br J Cancer. 2018;118(9) :1176-1178. 3. Choueiri TK, Hessel C, Halabi S, et al. Cabozantinib versus sunitinib as initial therapy for metastatic renal cell carcinoma of intermediate or poor risk {Alliance A031203 CABOSUN randomised trial}: Progression-free survival by independent review and overall survival update. Eur J Cancer. 201 8;94:115-125. 4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. Version 2.2020 - August 2019. 5. Escudier B, Porta C, Schmidinger M, et al. Renal cell carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oneal. 2019;30(5):706-720. 6. European Medicines Agency. Committee for Medicinal Products for Human Use {CHMP). Assessment report: cabozantinib, 2018. Available from: www.ema.europa Accessed May 2020.7. Abou-Alfa GK, MeyerT, Cheng AL, et al. Cabozantinib in patients with advanced and progressing hepatocellular carcinoma. N Engl J Med.2018;379{1):54-63. 8. Vogel A, Cervantes A, Chau I, et al. Hepatocellular carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oneal. 2018; 29(Supplement_ 4): iv238-255. 9. Galle PR, Forner A, Llovet JM. et al. EASL clinical practice guidelines: management ot hepatocellular carcinoma. J Hepatol. 2018;69(1):I 82-236. I 0. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Hepatobiliary cancers. Version 1.2020, March 2020. 11. CABOMETYX® Malaysia Prescribing Information (April 2021).

Cabometyx® Malaysia Abridged Prescribing Information
Trade Name: Cabometyx® 20 / 40 / 60 mg film-coated tablets. **INN:** Cabozantinib. **Presentations:** Film-coated tablets, HDPE bottle with a polypropylene child-resistant closure and three silica gel dessicant canisters. Each bottle contains 30 film-coated tablets. **Posology & Administration:** Treatment should be initiated by a physician experienced in the administration of anticancer medicinal product. The recommended dose is 60 mg once daily. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. Management of suspected adverse drug reactions may require temporary interruption and/or dose reduction of Cabometyx® therapy. When dose reduction is necessary, it is recommended to reduce to 40 mg daily, and then to 20 mg daily. Dose interruptions are recommended for management of CTCAE grade 3 or greater toxicities or intolerable grade 2 toxicities. Dose reductions are recommended for events that, if persistent, could become serious or intolerable. If a patient misses a dose, the missed dose should not be taken if it is less than 12 hours before the next dose. Oral use: tablets should be swallowed whole and not crushed. Patients should be instructed to not eat anything for at least 2 hours before through 1 hour after taking the drug. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients stated. **Special Warnings & Precautions:** Physicians should evaluate closely the patient during the first 8 weeks of treatment to determine if dose modifications are warranted. Caution should be given to patients with gastrointestinal diseases or risks, thromboembolic events risks or history, haemorrhage risks or history, hypertension. Some undesirable effects might occur such as: palmar-plantar erythrodysaesthesia syndrome, proteinuria, reversible posterior leukoencephalopathy syndrome, prolongation of QT interval. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose go lactose malabsorption should not take this medicine. **Interactions:** CYP 3A4 inducers and inhibitors, P-glycoproteins substrates, MRP2 inhibitors, gastric pH modifying agents, bile salt-sequestering agents. **Pregnancy, Lactation & Fertility:** Pregnancy should be avoided while on cabozantinib, or while the partner is taking cabozantinib; an effective method of contraception should be used by both partners during treatment and for at least 4 months after completing therapy, along with a barrier method. Mothers should discontinue breast-feeding during the treatment. Male and Female fertility may be compromised by treatment with cabozantinib. **Ability to Drive & Use Machines:** Caution should be recommended when driving or operating machines while on cabozantinib. **Undesirable Effects:** Abdominal pain, diarrhea, nausea, fatigue, decreased appetite, palmar-plantar erythrodysaesthesia syndrome, hypertension, vomiting, weight decreased and constipation. **Reference:** Cabometyx® Malaysia Prescribing Information {April 2021). **Date of preparation:** April 2021.

All adverse events should be reported to pharmacovigilance.global@ipsen.com
Full prescribing information is available upon request, please refer to full prescribing information before prescribing.

CMX-MY-000043 June 2021

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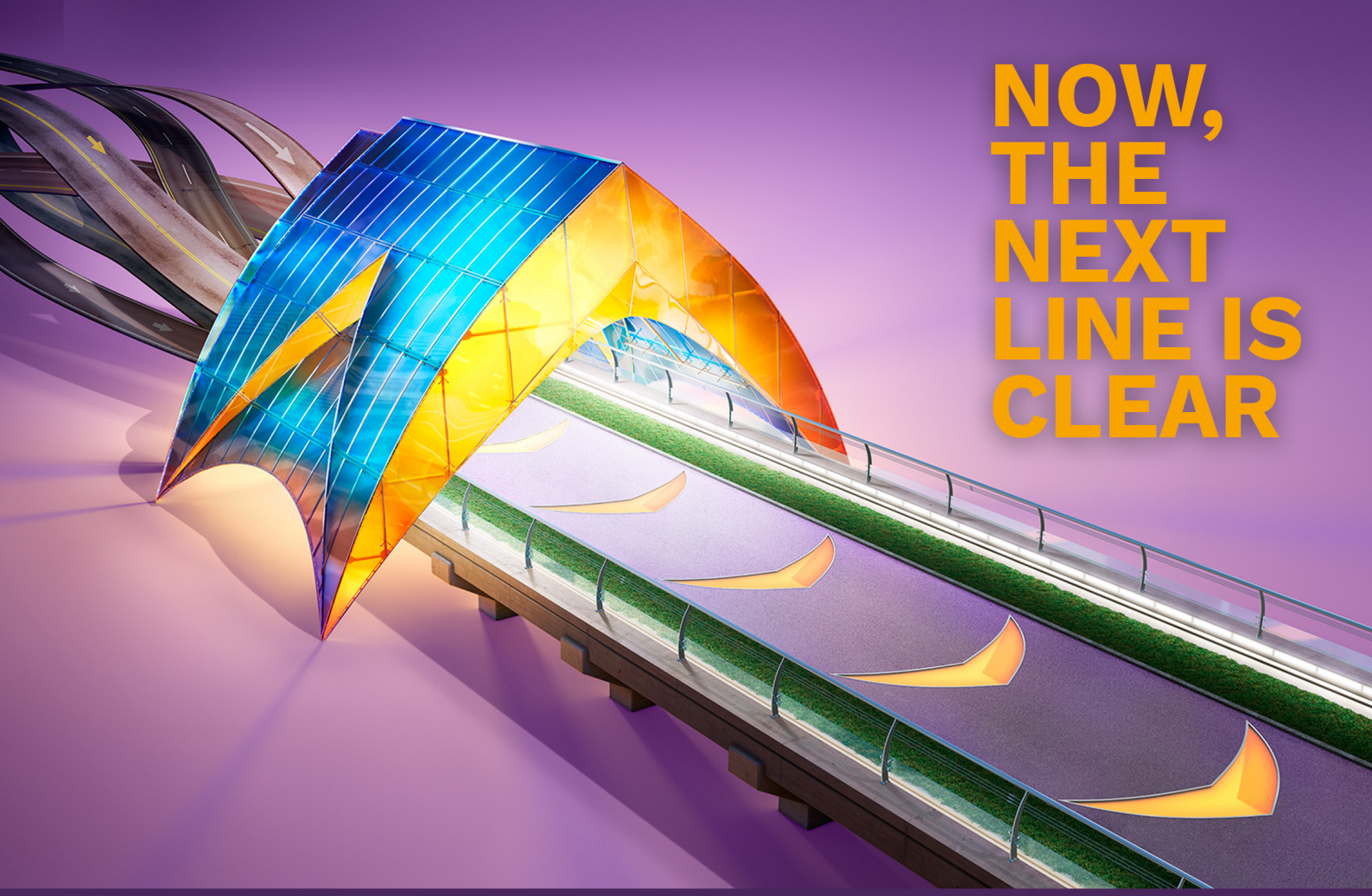

LORVIQUA® OFFERS HOPE TO PATIENTS WHOSE DISEASE HAS PROGRESSED ON A SECOND-GENERATION ALK TKI[1,2]

LORVIQUA®	A potent third-generation ALK TKI designed to address the unmet medical needs of CNS progression and ALK resistance mutations[2–4]
LORVIQUA®	Demonstrated efficacy in patients whose disease has progressed on a second-generation ALK TKI[1,2]
LORVIQUA®	Manageable safety profile with a low discontinuation rate[2]
LORVIQUA®	Improved or stable QoL scores and symptoms, with protection against CNS progression[5,6]

Consider prescribing LORVIQUA® as early as possible for your patients whose disease has progressed on a second-generation ALK TKI[1]

LORVIQUA® as monotherapy is indicated for the treatment of adult patients with ALK+ advanced NSCLC whose disease has progressed after alectinib or ceritinib as the first ALK TKI therapy; or crizotinib and at least one other ALK TKI.[1]

Lorviqua® Abbreviated Prescribing Information[1]
Lorviqua® (Lorlatinib) film-coated tablets, oral.
PRESENTATION: Lorlatinib 25mg and 100mg film-coated tablets. Available in aluminum blister foil 3,6,9 or 12 blister strips with 10 tablets each for 25mg, and blister foil of 1 or 3 blister strip with 10 tablets for 100mg. **INDICATIONS AND USAGE:** Lorviqua® as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitors (TKI) therapy; or crizotinib and at least one other ALK TKI. This indication is approved under conditional registration which is based on tumor objective response rate and duration of response. Continued approval for this indication may be based on the outcome of clinical benefit in a confirmatory trial. **DOSAGE AND ADMINISTRATION:** 100 mg taken orally once daily continuously. Continue treatment as long as the patient is deriving clinical benefit from therapy. Lorviqua® may be taken with or without food. **CONTRAINDICATIONS:** Hypersensitivity to lorlatinib or to any of the excipients listed. Concomitant use of strong CYP3A inducers with lorlatinib is contraindicated due to the potential for serious hepatotoxicity (aspartate aminotransferase [AST] and alanine aminotransferase [ALT] elevations). **WARNINGS AND PRECAUTIONS:** HYPERLIPIDAEMIA: The use of lorlatinib has been associated with increases in serum cholesterol and triglycerides. Serum cholesterol and triglycerides should be monitored before initiation of lorlatinib; 2, 4, and 8 weeks after initiating lorlatinib; and periodically thereafter. Initiation, or increase in the dose, of lipid-lowering agents is required. CENTRAL NERVOUS SYSTEM EFFECTS (CNS): CNS effects have been observed including psychotic effects, changes in cognitive function, mood, speech, and mental status changes. Dose modification or discontinuation may be required. ATRIOVENTRICULAR BLOCK: PR interval prolongation and atrioventricular (AV) block events have been reported. Monitor electrocardiogram (ECG) prior to initiating lorlatinib and monthly thereafter, particularly in patients with predisposing conditions to the occurrence of clinically significant cardiac events. Dose modification may be required. LEFT VENTRICULAR EJECTION FRACTION (LVEF) DECREASE: LVEF decrease has been reported in patients who had baseline and at least one follow-up LVEF assessment. In patients with cardiac risk factors and those with conditions that can affect LVEF, cardiac monitoring, including LVEF assessment at baseline and during treatment, should be considered. In patients who develop relevant cardiac signs/symptoms during treatment, cardiac monitoring, including LVEF assessment, should be considered. LIPASE AND AMYLASE INCREASE: Risk of pancreatitis should be considered. Patients should be monitored for lipase and amylase elevations prior to the start of lorlatinib treatment and regularly thereafter as clinically indicated. PNEUMONITIS: Severe or life-threatening pulmonary adverse reactions consistent with pneumonitis have occurred with lorlatinib. Lorlatinib should be withheld and/or permanently discontinued based on severity. HYPERTENSION: Blood pressure should be controlled prior to initiation of lorlatinib. Blood pressure should be monitored after 2 weeks and at least monthly thereafter during treatment with lorlatinib. Lorlatinib should be withheld and resumed at a reduced dose or permanently discontinued based on severity HYPERGLYCAEMIA: Fasting serum glucose should be assessed prior to initiation of lorlatinib and monitored periodically thereafter. Lorlatinib should be withheld and resumed at a reduced dose or permanently discontinued based on severity. DRUG-DRUG INTERACTIONS: Concomitant use of any strong CYP3A inducer is contraindicated. Any strong CYP3A inducers have to be discontinued for at least 3 plasma half-lives of the strong CYP3A inducer before lorlatinib treatment is started. FERTILITY AND PREGNANCY: Women of childbearing potential should be advised to avoid becoming pregnant while receiving Lorviqua®. A highly effective non-hormonal method of contraception is required for female patients because lorlatinib can render hormonal contraceptives ineffective. Male fertility may be compromised, and men should seek advice on effective fertility preservation before treatment. **UNDESIRABLE EFFECTS:** The very common (≥1/10) and common (≥1/100 to <1/10) adverse reactions of any grade reported in patients treated with Lorviqua® were anemia, hypercholesterolaemia, hypertriglyceridaemia, mood effects, psychotic effects, mental status changes, cognitive effects, peripheral neuropathy, headache, speech effects, vision disorder, pneumonitis, diarrhoea, nausea, constipation, rash, arthralgia, myalgia, oedema, fatigue, weight increased, lipase increased, amylase increased.

API-LORVIQUA®-0221
Full prescribing information available upon request

References: 1. Lorviqua® Malaysia Prescribing Information CLD dated 2 February 2021. **2.** Solomon BJ, Besse B, Bauer TM, et al. Lorlatinib in patients with ALK-positive non-small-cell lung cancer: results from a global phase 2 study. Lancet Oncol. 2018. doi: 10.1016/S1470-2045(18)30649-1. /[Epub ahead of print]. **3.** Johnson TW, Richardson PF, Bailey S, et al. Discovery of (10R)-7-amino-12-fluoro-2,10,16-trimethyl-15-oxo-10,15,16,17-tetrahydro-2H-8,4-(metheno)pyrazolo[4,3-h][2,5,11]-benzoxadiazacyclotetradecine-3-carbonitrile (PF-06463922), a macrocyclic inhibitor of anaplastic lymphoma kinase (ALK) and c-ros oncogene 1 (ROS1) with preclinical brain exposure and broad-spectrum potency against ALK-resistant mutations. J Med Chem. 2014;57(11):4720–44. **4.** Gainor JF, Dardaei L, Yoda S, et al. Molecular mechanisms of resistance to first- and second-generation ALK inhibitors in ALK-rearranged lung cancer. Cancer Discov. 2016;6(10):1118–33. **5.** Peters S, Shaw AT, Besse B, et al. Impact of lorlatinib on patient-reported outcomes in patients with advanced ALK-positive or ROS1-positive non-small-cell lung cancer. Lung Cancer 2020;144:10-19. **6.** Bauer TM, Shaw AT, Johnson ML, et al. Brain penetration of lorlatinib: cumulative incidences of CNS and non-CNS progression with lorlatinib in patients with previously treated ALK-positive non-small-cell lung cancer. Targeted Oncology 2020;15:55-65.

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Across the world, Dr. Reddy's
strives to provide high-quality medicine at affordable prices

Data on file *Updated as on Month – January 2021.

Abbreviated Product Information

Trade Name: Eranfu® **Active Ingredient:** Fulvestrant 250mg/5mL **Therapeutic Indications:** Fulvestrant is indicated for the treatment of: i) estrogen receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy, ii) estrogen receptor-positive, locally advanced or metastatic breast cancer in postmenopausal women with disease relapse on or after adjuvant endocrine therapy, or disease progression on endocrine therapy. **Dosage & administration:** In adult females (including elderly), the recommended dose is 500 mg at intervals of one month, with an additional 500 mg dose given two weeks after the initial dose. Fulvestrant should be administered as two consecutive 5 ml injections by slow intramuscular injection (1-2 minutes/injection), one in each buttock (gluteal area). No dose adjustments are recommended for patients with mild to moderate renal impairment (creatinine clearance ≥ 30 ml/min). No dose adjustments are recommended for patients with mild to moderate hepatic impairment. Administer the injection according to the local guidelines for performing large volume intramuscular injections. **Contraindications:** Hypersensitivity to the active substance, or to any of the other excipients, pregnancy and lactation, severe hepatic impairment. **Warnings & precautions:** Fulvestrant should be used with caution in patients with mild to moderate hepatic impairment and in patients with severe renal impairment (creatinine clearance less than 30 ml/min). Due to the IM administration, fulvestrant should be used with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment. Thromboembolic events are commonly observed in women with advanced breast cancer. This should be taken into consideration when prescribing fulvestrant to patients at risk. Injection site related events including sciatica, neuralgia, neuropathic pain and peripheral neuropathy have been reported with fulvestrant injection. Caution should be taken while administering fulvestrant at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve. There are no long-term data on the effect of fulvestrant on bone. Due to the mechanism of action of fulvestrant, there is a potential risk of osteoporosis. Due to the structural similarity of fulvestrant and estradiol, fulvestrant may interfere with antibody based-estradiol assays and may result in falsely increased levels of estradiol. **Undesirable effects:** The most common adverse reactions occurring in patients receiving fulvestrant 500 mg were: injection site pain, nausea, bone pain, arthralgia, headache, back pain, fatigue, and pain in extremity, hot flash, vomiting, anorexia, asthenia, musculoskeletal pain, cough, dyspnea, and constipation. Increased hepatic enzymes (ALT, AST, ALP). **Storage:** Store in refrigerator at 2°C to 8°C. Do not freeze. Store the pre-filled syringe in the original package, in order to protect from light. **Presentations:** 2 pre-filled syringes in a carton.

Full information available on request. Please consult full prescribing information before prescribing.

Dr.Reddy's

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DRL/MY/Eranfu 250mg-003/Feb2021

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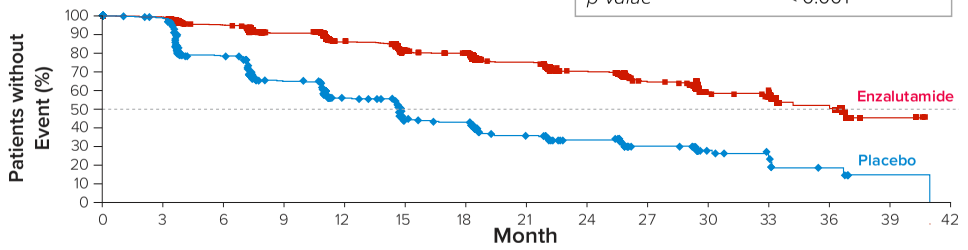
MFS is significantly delayed among patients of high-risk nmCRPC treated with Xtandi™ vs. placebo[1]

Kaplan-Meier analysis of MFS

	Enzalutamide (*n* = 872)	Placebo (*n* = 845)
Median (95% CI), mo	36.6 (33.1-NR)	14.7 (14.2-15.0)
HR (95% CI)	0.29 (0.24-0.35)	
p-value	< 0.001	



No. at Risk															
Enzalutamide	933	865	759	637	528	431	418	328	237	159	87	77	31	4	0
Placebo	468	420	296	212	157	105	98	64	49	31	16	11	5	1	0

NR denotes not reached.
Adapted from Hussain MD, et al. New Engl J Med. 2018.

Start Xtandi™ as soon as your nmCRPC patients progress on ADT with a PSA DT of < 10 months

ADT, androgen deprivation therapy; CI: confidence interval; HR: hazard ratio; MFS: metastatic-free survival; nmCRPC: non-metastatic castrate-resistant prostate cancer; NR: not reached; PSADT: prostate-specific antigen doubling time.

XTANDI™ Abbreviated Prescribing Information

Presentation: Soft Capsules containing 40 mg of enzalutamide. **Indications:** Treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC).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 soft capsules should not be chewed, dissolved or opened but 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: Use of enzalutamide has been associated with seizure (see section 4.8). 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. Hypersensitivity reactions: Hypersensitivity reactions manifested by symptoms including, but not limited to, rash, or face, tongue, lip, or pharyngeal oedema, have been observed with enzalutamide (see section 4.8). **Undesirable Effects:** Summary of the safety profile: The most common adverse reactions are asthenia/fatigue, hot flush, fractures, and hypertension. Other important adverse reactions include fall, cognitive disorder, and neutropenia. Seizure occurred in 0.4% 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 (see section 4.4). 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 (Spontaneous reports from post-marketing experience, 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. Immune system disorders: *not known*:* face oedema, tongue oedema, lip oedema, pharyngeal oedema. Psychiatric disorders: *common:* anxiety; *uncommon:* visual hallucinations. Nervous system disorders: *common:* headache, memory impairment, amnesia, disturbance in attention, restless legs syndrome; *uncommon:* cognitive disorder, seizure; *not known:* posterior reversible encephalopathy syndrome. Cardiac disorders: *common:* ischemic heart disease. Vascular disorders: *very common:* hot flush, hypertension. Gastrointestinal disorders: *not known:* nausea, vomiting, diarrhea. Skin and subcutaneous tissue disorders: *common:* dry skin, pruritus; *not known:* rash. Musculoskeletal and connective tissue disorders: *very 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. Reproductive system and breast disorder: *common:* gynaecomastia. General disorders and administration site conditions: *very common:* asthenia, fatigue. Injury, poisoning and procedural complications: *common:* falls. *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 9785-CL-0403 (UPWARD) 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. 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. *Ischemic Heart Disease:* In randomized placebo-controlled clinical studies, ischemic heart disease occurred in 2.7% of patients treated with enzalutamide plus ADT compared to 1.3 % patients treated with placebo plus ADT. **Packs:** 112 soft capsules of 40 mg. **API date:** 09032021.

Please refer to the full prescribing information before prescribing XTANDI™.

Reference
1. Hussain M, Fizazi K, Saad F, *et al*. Enzalutamide in men with nonmetastatic, castration-resistant prostate cancer. *New Engl J Med.* 2018;378(26):2465-74.

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