Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 390, 3 November 2023

Products approved for additional indication (DCA 390 – 3 November 2023)

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>1.</td><td>Lynparza 100 mg Film-Coated Tablets

[Olaparib 100 mg]

Lynparza 150 mg Film-Coated Tablets

[Olaparib 150 mg]</td><td>
INDICATION :

<u>Prostate cancer</u>

Lynparza is indicated:

• in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).

POSOLOGY :

Table 1 Biomarker Testing for Patient Selection
<table>
<tr><th rowspan="2">Indication</th><th rowspan="2">Biomarker</th><th colspan="2">Sample Type</th></tr>
<tr><th>Tumour</th><th>Blood</th></tr>
<tr><td>BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone</td><td>BRCA1m, BRCA2m</td><td>X</td><td>X</td></tr>
</table>
BRCA-mutated Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone:
Continue treatment until disease progression or unacceptable toxicity.

When used with Lynparza, the recommended dose of abiraterone is 1000 mg taken orally once daily. Abiraterone should be given in combination with prednisone or prednisolone 5 mg orally twice daily. Refer to the Prescribing Information for abiraterone for dosing information.

Patients with mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.
</td><td>ASTRAZENECA SDN. BHD.
Level 11 & 12, The Bousteador,
No. 10, Jalan PJU 7/6,
Mutiara Damansara,
47800 Petaling Jaya,
Selangor.</td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Dymista Nasal Spray 137mcg/50mcg [Azelastine Hydrochloride 137mcg/ Fluticasone Propionate 50mcg]	**INDICATION :** Symptomatic treatment of moderate to severe allergic rhinitis and rhino-conjunctivitis in adults and children 6 years and older where use of a combination (intranasal antihistamine and glucocorticoid) is appropriate. **POSOLOGY :** <u>Adults, adolescents and children (e.g. 6 years and older)</u> One spray in each nostril twice daily (morning and evening). <u>Children below 6 years</u> DYMISTA nasal spray is not recommended for use in children below 6 years of age as safety and efficacy has not been established in this age group.	**MYLAN HEALTHCARE SDN. BHD.** 15-03 & 15-04, Level 15, Imazium, No. 8, Jalan SS 21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 390 – 3 November 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Zavicefta (Ceftazidime 2g/Avibactam 0.5g) Powder for Concentrate for Solution for Infusion [Avibactam Sodium 550.7mg, equivalent to 500mg of avibactam and Ceftazidime Pentahydrate 2360.7mg, equivalent to 2000mg of ceftazidime]	**INDICATION :** Zavicefta is indicated in adults and pediatric patients aged 3 months and older for the treatment of the following infections (see sections 4.4 Special warnings and precautions for use and 5.1 Pharmacodynamic properties): • Complicated intra-abdominal infection (cIAI), in combination with metronidazole. • Complicated urinary tract infection (cUTI), including pyelonephritis. Zavicefta is indicated for the treatment of the following infections in adults (see sections 4.4 Special warnings and precautions for use and 5.1 Pharmacodynamic properties): • Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP). Treatment of adult patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Consideration should be given to official guidance on the appropriate use of antibacterial agents. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zavicefta and other antibiotics, Zavicefta should be used in combination with an antibacterial agent(s) active against Gram-positive and/or anaerobic pathogens when these are known or suspected to be contributing to the infectious process. **POSOLOGY :** Dosage in Adults with Creatinine Clearance (CrCL > 50 mL/min) Table 1 shows the recommended intravenous dose for adults with estimated creatinine clearance (CrCL) > 50 mL/min (See sections 4.4 Special Warnings and Precautions for Use and 5.1 Pharmacodynamic Properties).	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td colspan="5">Table 1 Recommended dose for adults with estimated CrCL > 50 mL/min1</td></tr>
<tr><td>Type of infection</td><td>Dose of ceftazidime/avibactam</td><td>Frequency</td><td>Infusion time</td><td>Duration of treatment</td></tr>
<tr><td>Bacteraemia

associated with, or suspected to be associated with any of the above infections</td><td>2 g/0.5 g</td><td>Every 8 hours</td><td>2 hours</td><td>Duration of

treatment should be in accordance with the site of infection.</td></tr>
</table>
[1]CrCL estimated using the Cockcroft-Gault formula.

<u>Dosage in paediatric patients with creatinine clearance (CrCL) > 50 mL/min/1.73 m^2</u>
Table 2 shows the recommended intravenous doses for paediatric patients with estimated creatinine clearance (CrCL) > 50 mL/min/1.73 m^2. (See sections 4.4 Special Warnings and Precautions for Use and 5.1 Pharmacodynamic Properties)
</td><td></td></tr>
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<tr><td></td><td></td><td>
Table 2: Recommended dose for paediatric patients with estimated CrCL[1] > 50 mL/min/1.73 m^2.
<table>
<tr><th>Type of infection</th><th>Age group</th><th>Dose of ceftazidime /avibactam[6]</th><th>Frequency</th><th>Infusion time</th><th>Duration of treatment</th></tr>
<tr><td rowspan="3">cIAI[2,3] or cUTI including pyelonephritis[3]</td><td rowspan="2">6 months to <18 years</td><td rowspan="2">50 mg/kg/12.5 mg/kg to a maximum of 2 g/0.5 g</td><td>Every 8 hours</td><td>2 hours</td><td rowspan="3">cIAI: 5 – 14 days
cUTI[4]: 5 – 14 days</td></tr>
<tr><td>Every 8 hours</td><td>2 hours</td></tr>
<tr><td>3 months to <6 months [5]</td><td>40 mg/kg/10 mg/kg</td><td>Every 8 hours</td><td>2 hours</td></tr>
</table>
[1] CrCL estimated using the Schwartz bedside formula.
[2] To be used in combination with metronidazole when anaerobic pathogens are known or suspected to be contributing to the infectious process.
[3] To be used in combination with an antibacterial agent active against Gram-positive pathogens when these are known or suspected to be contributing to the infectious process.
[4] The total treatment duration shown may include intravenous Zavicefta followed by appropriate oral therapy.
[5] There is limited experience with the use of Zavicefta in paediatric patients 3 months to < 6 months. (see section 5.2 Pharmacokinetic Properties)
[6] Ceftazidime/avibactam is a combination product in a fixed 4:1 ratio and dosage recommendations are based on the ceftazidime component only (see section 6.6 Instructions for use, handling and disposal).

<u>Special populations</u>

Renal impairment

No dosage adjustment is required in patients with mild renal impairment (estimated CrCL > 50 - ≤ 80 mL/min).
</td><td></td></tr>
</table>

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<tr><td></td><td></td><td>
Table 4 and Table 5 show the recommended dose adjustments for paediatric patients with estimated CrCL ≤ 50 mL/ min/1.73 m^2 according to different age groups.

<u>Dosage in paediatric patients ≥ 2 years of age with CrCl ≤ 50 mL/min/1.73 m^2</u>
<table>
<tr><th colspan="5">Table 4: Recommended dose for paediatric patients with estimated CrCL[1] ≤ 50 mL/min/1.73 m^2</th></tr>
<tr><th>Age Group</th><th>Estimated CrCL (mL/min/1.73 m^2)</th><th>Dose of ceftazidime / avibactam[2,4]</th><th>Frequency</th><th>Infusion time</th></tr>
<tr><td rowspan="4">Paediatric patients aged 2 years to <18 years</td><td>31-50</td><td>25 mg/kg/6.25 mg/kg to a maximum of 1 g/0.25 g</td><td>Every 8 hours</td><td rowspan="4">2 hours</td></tr>
<tr><td>16-30</td><td rowspan="3">18.75 mg/kg/4.7 mg/kg to a maximum of 0.75 g/0.1875 g</td><td>Every 12 hours</td></tr>
<tr><td>6-15</td><td>Every 24 hours</td></tr>
<tr><td>End Stage Renal Disease including on haemodialysis[3]</td><td>Every 48 hours</td></tr>
</table>
[1] CrCL estimated using the Schwartz bedside formula.
[2] Dose recommendations are based on pharmacokinetic modelling.
[3] Ceftazidime and avibactam are removed by haemodialysis. Dosing of Zavicefta on haemodialysis days should occur after completion of haemodialysis.
[4] Ceftazidime/avibactam is a combination product in a fixed 4:1 ratio and dosage recommendations are based on the ceftazidime component only.
</td><td></td></tr>
</table>

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<tr><td></td><td></td><td>
<u>Dosage in paediatric patients <2 years of age with CrCl ≤ 50 mL/min/1.73 m^2</u>
<table>
<tr><th colspan="5">Table 5: Recommended dose for paediatric patients with estimated CrCL[1] ≤ 50 mL/min/1.73 m^2</th></tr>
<tr><th>Age Group</th><th>Estimated CrCL (mL/min/1.73 m^2)</th><th>Dose of ceftazidime / avibactam[2,3]</th><th>Frequency</th><th>Infusion time</th></tr>
<tr><td>3 to < 6 months</td><td rowspan="2">31 to 50</td><td>20 mg/kg/5 mg/kg</td><td>Every 8 hours</td><td rowspan="3">2 hours</td></tr>
<tr><td>6 months
to < 2 years</td><td>25 mg/kg/6.25 mg/kg</td><td>Every 8 hours</td></tr>
<tr><td>3 to < 6 months</td><td rowspan="2">16 to 30</td><td>15 mg/kg/3.75 mg/kg</td><td>Every 12 hours</td></tr>
<tr><td>6 months
to < 2 years</td><td>18.75 mg/kg/4.7 mg/kg</td><td>Every 12 hours</td><td></td></tr>
</table>
[1] Calculated using the Schwartz bedside formula
[2] Dose recommendations are based on pharmacokinetic modelling.
[3] Ceftazidime/avibactam is a combination product in a fixed 4:1 ratio and dosage recommendations are based component only. (see section 6.6 Instructions for use, handling and disposal).

There is insufficient information to recommend a dosage regimen for paediatric patients < 2 years of age that have a CrCL < 16 mL/min/1.73 m^2.

Hepatic impairment

No dosage adjustment is required in patients with hepatic impairment (see section 5.2 Pharmacokinetic Properties).

Paediatric patients

The safety and efficacy in paediatric patients <3 months old have not been established. No data are available.
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** KEYTRUDA® as monotherapy is indicated for the adjuvant treatment of adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC who have undergone complete resection and platinum-based chemotherapy. **POSOLOGY :** General Patient Selection If specified in the indication, select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression, MSI-H or dMMR tumor status [see V. Indications]. PD-L1 expression should be evaluated using the PD-L1 IHC 22C3 pharmDx™ kit or equivalent. MSI or MMR tumor status should be evaluated using a validated test. Recommended Dosing KEYTRUDA is administered as an intravenous infusion over 30 minutes. The recommended dose of KEYTRUDA in adults is either: • 200mg every 3 weeks or • 400mg every 6 weeks. For use in combination, see the prescribing information for the concomitant therapies. When administering KEYTRUDA as part of a combination with intravenous chemotherapy, KEYTRUDA should be administered first.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		For RCC patients treated with KEYTRUDA in combination with axitinib, see the prescribing information regarding dosing of axitinib. When used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer [see Clinical Studies (IIId)]. For endometrial carcinoma and RCC patients treated with KEYTRUDA in combination with lenvatinib, the recommended initial dose of lenvatinib is 20 mg orally once daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e., an initial transient increase in tumor size or small new lesions within the first few months followed by tumor shrinkage) have been observed. Clinically stable patients with initial evidence of disease progression should remain on treatment until disease progression is confirmed. For adjuvant treatment of melanoma, NSCLC or RCC, KEYTRUDA should be administered for up to one year or until disease recurrence or unacceptable toxicity. For the neoadjuvant and adjuvant treatment of high-risk early-stage TNBC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks or until disease recurrence or unacceptable toxicity. Patients who experience disease progression that precludes definitive surgery or unacceptable toxicity related to KEYTRUDA as neoadjuvant treatment in combination with chemotherapy should not receive KEYTRUDA monotherapy as adjuvant treatment.	