Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 406, 4 Mac 2025

Products approved for additional indication (DCA 406 – 4 March 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	ONIVYDE pegylated liposomal 4.3 mg/ml concentrate for dispersion for infusion (Irinotecan anhydrous free base) [Irinotecan Hydrochloride Trihydrate]	**INDICATION :** ONIVYDE pegylated liposomal is indicated: - in combination with oxaliplatin, 5 fluorouracil (5 FU) and leucovorin (LV) for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas. **POSOLOGY :** *ONIVYDE pegylated liposomal should not be administered as a single agent and should be continued until disease progression or no longer tolerated by the patient.* *ONIVYDE pegylated liposomal in combination with oxaliplatin, 5-fluorouracil and leucovorin:* *ONIVYDE pegylated liposomal, oxaliplatin, LV and 5-FU should be administered sequentially. The recommended dose of ONIVYDE pegylated liposomal is 50 mg/m² intravenously over 90 minutes, followed by oxaliplatin 60 mg/m2 intravenously over 120 minutes, followed by LV 400 mg/m2 intravenously over 30 minutes, followed by 5-FU 2,400 mg/m2 intravenously over 46 hours. This regimen should be administered every 2 weeks.* *Oxaliplatin may be discontinued if not well tolerated and treatment with ONIVYDE pegylated liposomal + 5-FU/LV can continue.* *The recommended starting dose of ONIVYDE pegylated liposomal in patients known to be homozygous for UGT1A1*28 allele is unchanged and remains 50 mg/m2 administered intravenously over 90 minutes.* *ONIVYDE pegylated liposomal in combination with oxaliplatin, 5-fluorouracil and leucovorin:*	**SERVIER MALAYSIA SDN. BHD.** Unit No. 25-02, Level 25, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
Table 1: Recommended dose modifications for ONIVYDE pegylated liposomal + oxaliplatin/5-FU/LV
<table>
<tr><td>Toxicity grade (value) by NCI CTCAE†</td><td colspan="2">ONIVYDE pegylated liposomal/Oxaliplatin/5-FU adjustments</td></tr>
<tr><td colspan="3">Haematological toxicities</td></tr>
<tr><td><u>Neutropenia</u></td><td colspan="2">A new cycle of therapy should not begin until the absolute neutrophil count is ≥2,000/mm^3 (2x10^9/L)</td></tr>
<tr><td rowspan="4">Grade 3 or Grade 4 (<1,000 cells/mm^3) or Neutropenic fever</td><td>First occurrence</td><td>Reduce ONIVYDE pegylated liposomal dose to 80% of initial dose
Reduce oxaliplatin and 5-FU dose by 20%</td></tr>
<tr><td>Second occurrence</td><td>Reduce ONIVYDE pegylated liposomal dose to 65% of initial dose
Reduce oxaliplatin and 5-FU dose by an additional 15%</td></tr>
<tr><td>Third occurrence</td><td>Reduce ONIVYDE pegylated liposomal dose to 50% of initial dose
Reduce oxaliplatin and 5-FU dose by an additional 15%</td></tr>
<tr><td>Fourth occurence</td><td>Discontinue treatment</td></tr>
<tr><td><u>Thrombocytopenia</u>
<u>Leukopenia</u></td><td colspan="2">A new cycle of therapy should not begin until the platelet count is ≥100,000/mm^3 (100x10^9/L).

Dose modifications for leukopenia and thrombocytopenia are</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
			based on NCI CTCAE toxicity grading and are the same as recommended for neutropenia above.		
		Non-haematological toxicities‡			
		Diarrhoea	*A new cycle of therapy should not begin until diarrhoea resolves to ≤ Grade 1 (2-3 stools/day more than pre-treatment frequency).*		
		Grade 2	*A new cycle of therapy should not begin until diarrhoea resolves to ≤ Grade 1 (2-3 stools/day more than pre-treatment frequency).*		
		Grade 3 or 4	***First occurrence***	*Reduce ONIVYDE pegylated liposomal dose to 80% of initial dose Reduce oxaliplatin and 5-FU dose by 20%*	
			Second occurrence	*Reduce ONIVYDE pegylated liposomal dose to 65% of initial dose Reduce oxaliplatin and 5-FU dose by an additional 15%*	
			Third occurrence	*Reduce ONIVYDE pegylated liposomal dose to 50% of initial dose Reduce oxaliplatin and 5-FU dose by an additional15%*	
			Fourth occurrence	*Discontinue treatment*	
		*All other toxicities**	***First occurrence***	*Reduce ONIVYDE pegylated liposomal*	

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Grade 3 or 4		*dose to 80% of initial dose Reduce oxaliplatin and 5-FU dose by 20%*	
			Second occurrence	*Reduce ONIVYDE pegylated liposomal dose to65% of initial dose Reduce oxaliplatin and 5-FU dose by an additional 15%*	
			Third occurrence	*Reduce ONIVYDE pegylated liposomal dose to 50% of initial dose Reduce oxaliplatin and 5-FU dose by an additional 15%*	
			Fourth occurrence	*Discontinue treatment*	
		For Grade ≥ 3 nausea and vomiting	*Reduce dose only if occurs despite optimal anti-emetic therapy*		
		Hand foot syndrome: Grade 3 or 4	***First occurrence***	*Discontinue treatment*	
		Any grade neurocerebellar or ≥ Grade 2 cardiac toxicity	***First occurrence***	*Discontinue treatment*	

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<table>
<tr><td><u>Anaphylactic reaction</u></td><td>First occurrence</td><td>Discontinue treatment</td></tr>
<tr><td><u>Interstitial lung disease</u></td><td>First occurrence</td><td>Discontinue treatment</td></tr>
</table>
* Excludes asthenia and anorexia;

† NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events, current version

Patients homozygous for the UGT1A1*28 allele should initiate ONIVYDE pegylated liposomal at the same dose and the same dose reduction requirements should apply.
</td><td></td></tr>
</table>

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Products approved for additional indication (DCA 406 – 4 March 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	BRIDION 100MG/ML SOLUTION FOR INJECTION [Sugammadex 100mg/ml/]	**INDICATION :** Reversal of neuromuscular blockade induced by rocuronium or vecuronium in patients 2 years of age and older. **POSOLOGY :** Pediatric population: <u>Children and adolescents (2 years and older):</u> Bridion 100 mg/ml may be diluted to 10 mg/ml to increase the accuracy of dosing in the pediatric population. **Routine reversal:** A dose of 4 mg/kg sugammadex is recommended for reversal of rocuronium or vecuronium induced blockade if recovery has reached at least 1 2 post tetanic counts (PTC). A dose of 2 mg/kg is recommended for reversal of rocuronium or vecuronium induced blockade at reappearance of T2. **Immediate reversal:** Immediate reversal in children and adolescents has not been investigated. <u>Term newborn infants and infants:</u> There is only limited experience with the use of sugammadex in infants (30 days to 2 years), and term newborn infants (less than 30 days) have not been studied. The use of sugammadex in term newborn infants and infants is therefore not recommended until further data become available.	**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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Products approved for additional indication (DCA 406 – 4 March 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Tagrisso Film-Coated Tablet 40mg [Osimertinib 40mg] Tagrisso Film-Coated Tablet 80mg [Osimertinib 80mg]	**INDICATION :** TAGRISSO is indicated in combination with: • pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. **POSOLOGY :** Posology Combination therapy The recommended dose of TAGRISSO is 80 mg osimertinib once a day when taken with pemetrexed and platinum-based chemotherapy. Refer to the approved Package Insert for pemetrexed and cisplatin or carboplatin for the respective dosing information. Patients in the adjuvant setting should receive treatment until disease recurrence or unacceptable toxicity. Treatment duration for more than 3 years was not studied. Patients with locally advanced or metastatic lung cancer should receive TAGRISSO treatment until disease progression or unacceptable toxicity. Dose adjustments Combination therapy When TAGRISSO is used in combination, any of the treatment components should be dose modified, as appropriate. For TAGRISSO dose modification instructions, see Table 1. The pemetrexed, cisplatin or carboplatin dose should be modified in accordance with the instructions in their respective approved Package Insert. Cisplatin and/or carboplatin should be used for up to 4 cycles.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 406, 4 Mac 2025

Products approved for additional indication (DCA 406 – 4 March 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Tivicay 50mg Film-Coated Tablets [Dolutegravir 50mg]	**INDICATION :** Tivicay is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and children aged at least 6 years. **POSOLOGY :** Children aged at least 6 years and weighing at least 20 kg. In patients infected with HIV-1 without resistance to the integrase class, (6 to less than 12 years of age and weighing at least 20 kg), the recommended dose of dolutegravir film coated tablets is 50 mg once daily. There is insufficient and efficacy data available to recommend a dose for dolutegravir 50 mg film coated tablets in children below age 6 or weighing less than 20 kg. There is insufficient data to recommend a dose of dolutegravir film coated tablets in integrase inhibitor resistance children.	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 406 – 4 March 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	Nucala 100mg/ml Solution for Injection in pre-filled syringe (Safety Syringe) Nucala 100mg/ml Solution for Injection in pre-filled pen (Autoinjector) [Mepolizumab 100mg/ml]	**INDICATION :** Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Nucala is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. **POSOLOGY :** Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Adults The recommended dose of mepolizumab is 100 mg administered subcutaneously once every 4 weeks. Nucala is intended for long-term treatment. Consideration can be given to alternative treatments in patients who have shown no response after 24 weeks of treatment for CRSwNP. Some patients with initial partial response may subsequently improve with continued treatment beyond 24 weeks. Children The safety and efficacy in children with CRSwNP below the age of 18 years have not been established. No data are available.	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.