Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 426, 5 November 2026

Products approved for additional indication (DCA 426 – 5 November 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Vemlidy (tenofovir alafenamide 25mg) film-coated tablets [Tenofovir alafenamide fumarate 28.04 mg (equivalent to 25 mg of tenofovir alafenamide free base)]	**INDICATION:** Vemlidy is indicated for the treatment of chronic hepatitis B (CHB) in paediatric patients 6 years of age and older weighing at least 25 kg. **POSOLOGY:** Adults and paediatric patients at least 6 years of age and older weighing at least 25 kg: one tablet once daily. Special populations Paediatric population The safety and efficacy of Vemlidy in children younger than 6 years of age, and or weighing < 25 kg, have not yet been established. No data are available.	**GILEAD SCIENCES MALAYSIA SDN. BHD.** Level 22, Axiata Tower, 9, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.
2.	YERVOY 5 mg/ml concentrate for solution for infusion [Ipilimumab 5mg/mL]	**INDICATION:** Mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) colorectal cancer (CRC) YERVOY in combination with nivolumab is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) colorectal cancer in the following setting: • first-line treatment of unresectable or metastatic colorectal cancer	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		POSOLOGY: <u>MSI/MMR testing</u> If specified in the indication, patient selection for treatment with YERVOY based on MSI-H/dMMR tumour status should be assessed by a CE-marked IVD with the corresponding intended purpose. If the CE-marked IVD is not available, an alternative validated test should be used (see sections 4.1, 4.4, and 5.1). dMMR or MSH-I colorectal cancer The recommended dose for first-line treatment of dMMR or MSI-H CRC is 1 mg/kg ipilimumab in combination with 240 mg of nivolumab administered intravenously every 3 weeks for a maximum of 4 doses, followed by nivolumab monotherapy is administered intravenously at either 240 mg every 2 weeks or at 480 mg every 4 weeks, as presented in Table 3. For the monotherapy phase, the first dose of nivolumab should be administered 3 weeks after the last dose of the combination of nivolumab and ipilimumab. Treatment with nivolumab is recommended until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.	

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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 3: Recommended doses and infusion times for intravenous administration of ipilimumab in combination with nivolumab for dMMR or MSI-H CRC

<table><tr><th></th><th>Combination phase, every 3 weeks for 4 dosing cycles</th><th>Monotherapy phase</th></tr><tr><td>Nivolumab</td><td>240 mg over 30 minutes</td><td>240 mg every 2 weeks over 30 minutes or
480 mg every 4 weeks over 30 minutes</td></tr><tr><td>Ipilimumab</td><td>1 mg/kg over 30 minutes</td><td>-</td></tr></table></td><td></td></tr>
<tr><td>3.</td><td>Arexvy Powder and suspension for suspension for injection

[Respiratory Syncytial Virus Pre-Fusion Protein 3 (RSVPreF3) antigen 120 mcg]</td><td>INDICATION:
Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

POSOLOGY:
No change of posology</td><td>GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.

HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.</td></tr>
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