Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 424, 3 September 2026

Products approved for additional indication (DCA 424 – 3 September 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	GLUCOPHAGE XR 500 mg Tablet [Metformin hydrochloride 500 mg] Glucophage XR 750mg Tablet [Metformin hydrochloride 750 mg] Glucophage XR 1000mg Extended release tablet [Metformin hydrochloride 1000 mg]	**INDICATION:** <u>Polycystic ovary syndrome (PCOS)</u> Ovulation stimulation to support conception in women with PCOS. Glucophage XR can be used as monotherapy or in combination with other treatment options. However, Glucophage XR is indicated only for patients with obesity, impaired glucose tolerance, or insulin resistance. **POSOLOGY:** **Ovulation stimulation to support conception in women with PCOS:** The usual dose is 1,500-2000 mg once daily. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose is 2000 mg once daily with the evening meal. Glucophage XR should be considered for at least 6 months. The decision to maintain therapy after conception and during pregnancy should be made clinically on a case-by-case basis, taking into consideration the patient needs and an evaluation of the potential risks and benefits.	**MERCK SDN. BHD.** B-23A-1, Level 23A, 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)
2.	Aquipta Tablet 10mg [Atogepant 10.0 mg (equivalent to atogepant free base monohydrate 10.3 mg)] Aquipta Tablet 60mg [Atogepant 60.0 mg (equivalent to atogepant free base monohydrate 61.8 mg)]	**INDICATION:** AQUIPTA is indicated for: • Acute treatment of migraine with or without aura in adults **POSOLOGY:** The maximum dose per day for AQUIPTA is 60 mg. For acute treatment of migraine as needed, the recommended dose for AQUIPTA is 60 mg.	**ABBVIE SDN BHD** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.
3.	IMFINZI CONCENTRATE FOR SOLUTION FOR INTRAVENOUS INFUSION 50 MG/ML [Durvalumab 50 mg/mL]	**INDICATION:** <u>Gastric or gastroesophageal junction adenocarcinoma</u> IMFINZI in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single-agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 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>
POSOLOGY:
<table>
<tr><th>Indication</th><th>Recommended IMFINZI dosage</th><th>Duration of Therapy</th></tr>
<tr><td>Neoadjuvant and
Adjuvant
Treatment of Resectable
GC/GEJC</td><td>Patients with body weight of more than 30 kg:
Neoadjuvant: IMFINZI 1500 mg every 4 weeks with FLOT [a,i] for up to 2 cycles prior to surgery
Adjuvant: IMFINZI 1500 mg every 4 weeks with FLOT [a,i] for up to 2 cycles, followed by IMFINZI 1500 mg as a single agent every 4 weeks for up to 10 cycles
Patients with body weight of 30 kg or less:
Neoadjuvant: IMFINZI 20 mg/kg every 4 weeks with FLOT [a,i] for up to 2 cycles prior to surgery
Adjuvant: IMFINZI 20 mg/kg every 4 weeks with FLOT [a,i] for up to 2 cycles, followed by IMFINZI 20 mg/kg as a single agent every 4 weeks for up to 10 cycles</td><td>Neoadjuvant: Until disease progression that precludes definitive surgery or unacceptable toxicity
Adjuvant: Until progression or recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery</td></tr>
</table>
[a] Administer IMFINZI prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the agent(s) administered in combination with IMFINZI for recommended dosage information, as appropriate.
[i] FLOT chemotherapy is administered on days 1 and 15 of each 4 week cycle [See Clinical Studies].
</td><td></td></tr>
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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Nucala 100mg/ml Solution for Injection in pre-filled pen (Autoinjector) Nucala 100mg/ml Solution for Injection in pre-filled syringe (Safety Syringe) [Mepolizumab 100mg/ml]	**INDICATION:** Chronic obstructive pulmonary disease (COPD) Nucala is indicated in adults as an add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA) (see Pharmacodynamic properties). **POSOLOGY:** **COPD** **Adults** The recommended dose of mepolizumab is 100 mg administered subcutaneously once every 4 weeks. Nucala is intended for long-term treatment. The need for continued therapy is to be considered at least on an annual basis as determined by physician assessment of the patient's disease severity and level of control of exacerbations. **COPD in children less than 18 years old** There is no relevant use of mepolizumab in the paediatric population (under 18 years of age) for the indication of COPD.	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Hz.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.