Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 399, 1 Ogos 2024

Products approved for additional indication (DCA 399 – 1 August 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	ZOLADEX LA 10.8 MG [Goserelin (LHRH analogue) 10.8 mg]	**INDICATION :** Endometriosis: In the management of endometriosis, Zoladex LA 10.8mg alleviates symptoms, including pain, and reduces the size and number of endometrial lesions.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.
2.	Dupixent 300 mg Solution for Injection in Pre-filled Syringe [Dupilumab 300mg]	**INDICATION:** <u>Prurigo Nodularis</u> DUPIXENT is indicated for the treatment of adult patients with moderate to severe prurigo nodularis (PN) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids. **POSOLOGY:** Recommended Dosage for Prurigo Nodularis The recommended dosage of DUPIXENT for adult patients is an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week (Q2W). DUPIXENT can be used with or without topical corticosteroids.	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	IDELVION 250 IU powder and solvent for solution for injection [Albutrepenonacog Alfa 100 I.U] IDELVION 500 IU powder and solvent for solution for injection [Albutrepenonacog Alfa 200 I.U] IDELVION 1000 IU powder and solvent for solution for injection IDELVION 2000 IU powder and solvent for solution for injection [Albutrepenonacog Alfa 400 I.U]	**POSOLOGY :** Initiate treatment of IDELVION under the supervision of a physician experienced in the treatment of haemophilia B. The decision for an individual patient on the use of home treatment of bleeding and prophylaxis of bleeding in patients with haemophilia B should be made by the treating physician who should ensure that appropriate training is provided and the use is reviewed at intervals. <u>Previously untreated patients</u> The safety and efficacy of IDELVION in previously untreated patients is consistent with the known safety and efficacy profile of rIX-FP in adult and pediatric PTPs with hemophilia B. <u>Monitoring Laboratory Tests</u> To confirm adequate factor IX levels have been achieved and maintained, monitor plasma factor IX activity by performing the one-stage clotting assay. Factor IX results can be affected by the type of aPTT reagent used. Measurement with a one-stage clotting assay using a kaolin based aPTT reagent or Actin FS aPTT reagent will likely result in an underestimation of activity level.	**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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4.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** Non-Small Cell Lung Carcinoma KEYTRUDA is indicated for the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery. **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,	**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)
		KEYTRUDA should be administered first. 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 resectable NSCLC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 39 weeks 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	

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		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.	