Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 334 – 2 Mei 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Venclexta Film-Coated Tablets 10mg** [Venetoclax 10mg] 1.2 **Venclexta Film-Coated Tablets 50mg** [Venetoclax 50mg] 1.3 **Venclexta Film-Coated Tablets 100mg** [Venetoclax 100mg]	➢ Indication: *VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.* ➢ Posology: *Venclexta in Combination with Rituximab* *Start rituximab administration after the patient has completed the ramp-up schedule with Venclexta (see Table 1) and has received the 400 mg dose of Venclexta for 7 days.* *Patients should continue Venclexta 400 mg once daily for 24 months from Cycle 1 Day 1 of rituximab.*	**ABBVIE SDN BHD** 9th Floor Menara Lien Hoe No.8, Persiaran Tropicana Tropicana Golf & Country Resort 47410 Petaling Jaya, Selangor
2.	2.1 **Invokana 100mg Film-Coated Tablets** [Canagliflozin hemihydrate 102mg, equivalent to canagliflozin 100mg] 2.2 **Invokana 300mg Film-Coated Tablets** [Canagliflozin hemihydrate 306mg, equivalent to canagliflozin 300mg]	➢ Indication: *<u>Add-On Combination in Patients with Established Cardiovascular Disease</u>* *INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD).*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

3.	3.1 **Invega Sustenna 50 mg Prolonged Release Suspension for Intramuscular Injection** [Paliperidone palmitate 78 mg, equivalent to 50 mg paliperidone] 3.2 **Invega Sustenna 75 mg Prolonged Release Suspension for Intramuscular Injection** [Paliperidone palmitate 117 mg, equivalent to 75 mg paliperidone] 3.3 **Invega Sustenna 100 mg Prolonged Release Suspension for Intramuscular Injection** [Paliperidone palmitate 156 mg, equivalent to 100 mg paliperidone] 3.4 **Invega Sustenna 150 mg Prolonged Release Suspension for Intramuscular Injection** [Paliperidone palmitate 234 mg, equivalent to 150 mg paliperidone]	➢ Indication: *INVEGA SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.* ➢ Posology: *Schizoaffective disorder: Recommended initiation of INVEGA SUSTENNA is with a dose of 150 mg on treatment day 1 and 100 mg one week later, both administered in the deltoid muscle. The recommended monthly maintenance dose is within the range of 50 to 150 mg adjusted based on tolerability and/or efficacy using available strengths. The 25 mg strength was not studied in schizoaffective disorder. Following the second initiation dose, monthly maintenance doses can be administered in either the deltoid or gluteal muscle.* *Switching from other antipsychotic agents* *There are no systematically collected data to specifically address switching patients with schizophrenia or schizoaffective disorder from other antipsychotics to INVEGA SUSTENNA, or concerning concomitant administration with other antipsychotics.*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

4.	4.1 **Keytruda 100mg Solution for Infusion** [Pembrolizumab 100mg]	➢ Indication: *Melanoma* *KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma.* *Non-Small Cell Lung Carcinoma* *KEYTRUDA as monotherapy is indicated for the first-line treatment of patients with metastatic non-small cell lung carcinoma (NSCLC) whose tumors express PD-L1 with a ≥50% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations.* *KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.* ***KEYTRUDA, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of patients with metastatic squamous NSCLC**.* *KEYTRUDA as monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving KEYTRUDA.* *Head and Neck Cancer* *KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.* *This indication is approved based on the overall response rate (ORR) and durability of response. Continued approval for this indication may be contingent upon the verification of the results from the confirmatory clinical studies.*	**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

Urothelial Carcinoma
KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by a validated test.
This indication is approved based on tumour response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Classical Hodgkin Lymphoma
KEYTRUDA as monotherapy is indicated for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are transplant-ineligible and have failed BV.
This indication is approved based on the overall response rate (ORR) and durability of response. Continued approval for this indication may be contingent upon the verification of the results from the confirmatory clinical studies.

- Posology:

General
Patient Selection for Non-Small Cell Lung Carcinoma or Urothelial Carcinoma
Select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression in:
- *advanced NSCLC [see Clinical Studies].*
- *locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy [see Clinical Studies].*

Recommended Dosing
KEYTRUDA is administered as an intravenous infusion over 30

minutes every 3 weeks.
The recommended dose of KEYTRUDA is:

- *200 mg for head and neck cancer, urothelial carcinoma, classical Hodgkin Lymphoma or previously untreated NSCLC as monotherapy.*
- ***200mg for NSCLC in combination therapy**.*
- *2 mg/kg for melanoma or previously treated NSCLC as monotherapy.*

When administering KEYTRUDA as part of a combination with chemotherapy, KEYTRUDA should be administered first. See also the prescribing information for the chemotherapy agents administered in combination.

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.

Dose modifications
Withhold KEYTRUDA for adverse reactions including:

- *Immune-mediated pneumonitis - moderate (Grade 2; US National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE v.4))*
- *Immune-mediated colitis - moderate or severe (Grade 2 or 3)*
- *Immune-mediated nephritis - moderate (Grade 2)*
- *Immune-mediated endocrinopathies - severe or life-threatening (Grade 3 or 4)*
- *Hematological toxicity – life-threatening (Grade 4) in patients with cHL*
- *Immune-mediated hepatitis associated with: o Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 to 5 times upper limit of normal (ULN) or total bilirubin >1.5 to 3 times ULN*
- *Immune-mediated severe skin reactions (Grade 3) or suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)*

Resume KEYTRUDA in patients whose adverse reactions recover to Grade 0-1.

Permanently discontinue KEYTRUDA:

- *If corticosteroid dosing cannot be reduced to ≤10 mg prednisone or equivalent per day within 12 weeks*
- *If a treatment-related toxicity does not resolve to Grade 0-1 within 12 weeks after last dose of KEYTRUDA*
- *If another episode of any severe toxicity occurs*
- *For adverse reactions including:*
  - *Life-threatening (Grade 4) toxicity except for endocrinopathies that improve to Grade 2 or lower and are controlled with replacement hormones, or for hematological toxicity in patients with cHL in which KEYTRUDA should be withheld until adverse reactions recover to Grade 0-1.*
  - *Immune-mediated pneumonitis - severe or life-threatening (Grade 3 or 4) or recurrent moderate (Grade 2)*
  - *Immune-mediated nephritis - severe or life-threatening (Grade 3 or 4)*
  - *Immune-mediated hepatitis associated with:*
    - *AST or ALT >5 times ULN or total bilirubin >3 times ULN*
    - *For patients with liver metastasis who begin treatment with moderate (Grade 2) elevation of AST or ALT, if AST or ALT increases ≥50% relative to baseline and lasts ≥1 week*
  - *Immune-mediated severe skin reactions (Grade 4) or confirmed SJS or TEN*
  - *Infusion-related reactions - severe or life-threatening (Grade 3 or 4)*

Preparation and administration

- *Protect from light. Do not freeze. Do not shake.*
- *Equilibrate the vial of KEYTRUDA to room temperature.*
- *Prior to dilution, the vial of liquid can be out of refrigeration (temperatures at or below 25°C) for up to 24 hours.*
- *Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. KEYTRUDA is a clear to slightly opalescent, colorless to slightly yellow solution. Discard the vial if visible particles are observed.*
- *Withdraw the required volume up to 4 mL (100 mg) of KEYTRUDA and transfer into an intravenous bag containing*

		0.9% sodium chloride or 5% glucose (dextrose) to prepare a diluted solution with a final concentration ranging from 1 to 10 mg/mL. Mix diluted solution by gentle inversion. • *Do not freeze the infusion solution.* • *The product does not contain preservative. The diluted product should be used immediately. If not used immediately, diluted solutions of KEYTRUDA solutions may be stored at room temperature for a cumulative time of up to 6 hours. Diluted solutions of KEYTRUDA may also be stored under refrigeration at 2°C to 8°C; however, the total time from dilution of KEYTRUDA to completion of infusion should not exceed 24 hours. If refrigerated, allow the vials and/or IV bags to come to room temperature prior to use.* • *Administer infusion solution intravenously over 30 minutes using a sterile, non-pyrogenic, low-protein binding 0.2 to 5 µm in-line or add-on filter.* • *Do not co-administer other drugs through the same infusion line.* • *Discard any unused portion left in the vial.* ***Renal Impairment*** *No dose adjustment is needed for patients with mild or moderate renal impairment. KEYTRUDA has not been studied in patients with severe renal impairment.* ***Hepatic Impairment*** *No dose adjustment is needed for patients with mild hepatic impairment. KEYTRUDA has not been studied in patients with moderate or severe hepatic impairment.*	