Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 389, 5 Oktober 2023

Products approved for additional indication (DCA 389 – 5 October 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Opdivo 10mg/ml, Concentrate for solution for infusion [Nivolumab 10mg/ml]	**INDICATION :** Neoadjuvant treatment of NSCLC OPDIVO, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥ 4cm or node positive) non-small cell lung cancer (NSCLC). **POSOLOGY :** Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. <u>PD-L1 testing</u> If specified in the indication, patient selection for treatment with OPDIVO based on the tumour expression of PD-L1 should be confirmed by a validated test (see sections 4.1, 4.4, and 5.1). <u>Posology</u> <u>OPDIVO as monotherapy</u> The recommended dose of OPDIVO is 3 mg/kg administered intravenously over 30 minutes every 2 weeks. <u>OPDIVO in combination with cabozantinib (tablets)</u> <u>Renal cell carcinoma</u> The recommended dose is nivolumab administered intravenously at either 240 mg every 2 weeks or 480 mg every 4 weeks in combination with 40 mg cabozantinib (tablets) administered orally every day.	**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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<table>
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[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
Table 1: Recommended doses and infusion times for intravenous administration of nivolumab in combination with oral administration of cabozantinib (tablets) for RCC
<table>
<tr><th></th><th>Combination phase</th></tr>
<tr><td>Nivolumab</td><td>240 mg every 2 weeks over 30 minutes or
480 mg every 4 weeks over 30 minutes</td></tr>
<tr><td>Cabozantinib (tablets)</td><td>40 mg once daily</td></tr>
</table>

<u>OPDIVO in combination with Chemotherapy</u>

<u>Gastric, gastro-oesophageal junction or oesophageal adenocarcinoma</u>
The recommended dose is 360 mg nivolumab administered intravenously over 30 minutes in combination with fluoropyrimidine- and platinum-based chemotherapy administered every 3 weeks or 240 mg nivolumab administered intravenously over 30 minutes in combination with fluoropyrimidineand platinum-based chemotherapy administered every 2 weeks (see section 5.1). Treatment with nivolumab is recommended until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

<u>Neoadjuvant treatment of non small cell lung cancer</u>
The recommended dose is 360 mg nivolumab administered intravenously over 30 minutes in combination with platinum-based chemotherapy every 3 weeks for 3 cycles (see section 5.1).
</td><td></td></tr>
</table>

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<tr><th>No.</th><th>Product
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<tr><td>2.</td><td>Dupixent 200mg Solution for Injection in Pre-Filled Syringe

[Dupilumab 200mg]

Dupixent 300 mg Solution for Injection in Pre-filled Syringe

[Dupilumab 300mg]</td><td>INDICATION :

Atopic Dermatitis

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis 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 :

Atopic Dermatitis
Dosage in Pediatric Patients 6 Months to 5 Years of Age
The recommended dosage of DUPIXENT for pediatric patients 6 months to 5 years of age is specified in Table 1.

Table 1: Dosage of DUPIXENT for Subcutaneous Administration in Pediatric Patients 6 Months to 5 Years of Age with Atopic Dermatitis
<table><tr><th>Body Weight</th><th>Initial[a] and Subsequent Dosage</th></tr><tr><td>5 to less than 15 kg</td><td>200 mg (one 200 mg injection) every 4 weeks (Q4W)</td></tr><tr><td>15 to less than 30 kg</td><td>300 mg (one 300 mg injection) every 4 weeks (Q4W)</td></tr></table>For pediatric patients 6 months to 5 years of age with atopic dermatitis, no initial loading dose is recommended.</td><td>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.</td></tr>
</table>

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Products approved for additional indication (DCA 389 – 5 October 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	TS-ONE OD Tablet 20 [Tegafur 20 mg, Gimeracil 5.8 mg, Oteracil potassium 19.6 mg (equivalent to 15.8 mg oteracil free acid)] TS-ONE OD Tablet 25 [Tegafur 25 mg, Gimeracil 7.25 mg, Oteracil potassium 24.5 mg (equivalent to 19.7 mg oteracil free acid)]	**INDICATION :** TS-ONE® is indicated in adults • For the treatment of HER2-negative metastatic breast cancer when given as monotherapy. **POSOLOGY :** *The posology for HER2-negative breast cancer is the same as the approved posology for other indications given as monotherapy.*	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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<tr><td>4.</td><td>Lenvima 4 mg Hard Capsules

[Lenvatinib mesilate 4.90 mg (equivalent to lenvatinib 4 mg)]

Lenvima 10mg Hard Capsules

[Lenvatinib mesilate 12.25 mg (equivalent to lenvatinib 10 mg)]</td><td>INDICATION :

LENVIMA, in combination with pembrolizumab, is indicated for the treatment of adult patients with advanced or recurrent endometrial carcinoma (EC) who have disease progression on or following prior treatment with platinum-containing therapy in any setting and are not candidates for curative surgery or radiation.

POSOLOGY :

<u>Endometrial Carcinoma (EC)</u>

The recommended dosage of lenvatinib is 20 mg orally once daily, in combination with pembrolizumab either 200 mg every 3 weeks or 400mg every 6 weeks, administered as an intravenous infusion over 30 minutes, until unacceptable toxicity or disease progression.

Refer to the pembrolizumab prescribing information for additional dosing information.

Dose adjustment and Discontinuation for EC

For lenvatinib-related toxicities see Table 1. When administering lenvatinib in combination with pembrolizumab, interrupt, dose reduce, or discontinue lenvatinib as appropriate (see table 5). Withhold or discontinue pembrolizumab in accordance with the instructions in the prescribing information for pembrolizumab. No dose reductions are recommended for pembrolizumab.

Table 5 Dose modifications from recommended lenvatinib daily dose in EC

<table><tr><td>Starting Dose
in combination with pembrolizumab</td><td>20 mg orally once daily
(two 10 mg capsules)</td></tr><tr><td colspan="2">Persistent and Intolerable Grade 2 or Grade 3 Toxicities</td></tr></table></td><td>EISAI (MALAYSIA) SDN. BHD.
Unit 701D, Level 7, Tower D,
Uptown 5,
No.5, Jalan SS21/39,
Damansara Uptown,
47400 Petaling Jaya,
Selangor.</td></tr>
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<table>
<tr><td>Adverse Reaction</td><td>Modification</td><td>Adjusted Dose</td></tr>
<tr><td>First occurrence</td><td>Interrupt until resolved to Grade 0-1 or baseline</td><td>14 mg orally once daily
(one 10 mg capsule + one 4 mg capsule)</td></tr>
<tr><td>Second occurrence (same reaction or new reaction)</td><td>Interrupt until resolved to Grade 0-1 or baseline</td><td>10 mg orally once daily
(one 10 mg capsule)</td></tr>
<tr><td>Third occurrence (same reaction or new reaction)</td><td>Interrupt until resolved to Grade 0-1 or baseline</td><td>8 mg orally once daily
(two 4 mg capsules)</td></tr>
<tr><td colspan="3">Life-threatening toxicities (Grade 4): Discontinue[b]</td></tr>
<tr><td colspan="3">a. Limited data are available for doses below 8 mg.
b. Treatment should be discontinued in case of life-threatening reactions (e.g., Grade 4) with the exception of laboratory abnormalities judged to be non-life-threatening, in which case they should be managed as severe reactions (e.g., Grade 3).</td></tr>
</table>
</td><td></td></tr>
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