Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 385, 8 Jun 2023

Products approved for additional indication (DCA 385 – 8 June 2023)

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>1.</td><td>IMFINZI CONCENTRATE FOR SOLUTION FOR INTRAVENOUS INFUSION 50 MG/ML

[Durvalumab 50mg/ml]</td><td>
INDICATION :

Biliary Tract Cancers (BTC)

IMFINZI in combination with gemcitabine and cisplatin is indicated for the first-line treatment of adults with unresectable or metastatic biliary tract cancer (BTC).

POSOLOGY :

The recommended dosages for IMFINZI as a single agent and IMFINZI in combination with chemotherapy are presented in Table 1.

IMFINZI is administered as an intravenous infusion over 60 minutes.

Table 1. Recommended dosage of IMFINZI
<table>
<tr><th>Indication</th><th>Recommended IMFINZI dosage</th><th>Duration of Therapy</th></tr>
<tr><td>NSCLC</td><td>Patients with a body weight of <u>more than 30 kg</u>:

10 mg/kg every 2 weeks

or

1500 mg every 4 weeks

Patients with a body weight of 30 kg <u>or less</u>:

10 mg/kg every 2 weeks <u>until weight increases to greater than 30 kg</u></td><td>Until disease progression, unacceptable toxicity, or a maximum of 12 months</td></tr>
</table>
</td><td>ASTRAZENECA SDN. BHD.
Level 11 & 12, The Bousteador,
No. 10, Jalan PJU 7/6,
Mutiara Damansara,
47800 Petaling Jaya,
Selangor.</td></tr>
</table>

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<tr><td>ES-SCLC</td><td><u>Patients with a body weight of more than 30 kg:</u>

1500 mg in combination with chemotherapy[a] every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as monotherapy

<u>Patients with a body weight of 30 kg or less:</u>

20 mg/kg in combination with chemotherapy[a] every 3 weeks (21 days) for 4 cycles, followed by 20mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg</td><td>Until disease progression or unacceptable toxicity</td></tr>
<tr><td><u>BTC</u></td><td><u>Patients with a body weight of more than 36 kg:</u>

<u>1500 mg in combination with chemotherapy[a] every 3 weeks (21 days) up to 8 cycles, followed by 1500 mg every 4 weeks as monotherapy</u>

<u>Patients with a body weight of 36 kg or less:</u>

<u>20 mg/kg in combination with chemotherapy[a] dose every 3 weeks (21 days) up to 8 cycles, followed by monotherapy at 20 mg/kg every 4 weeks until weight increases to greater than 36 kg</u></td><td><u>Until disease progression or until unacceptable toxicity</u></td></tr>
</table>
<u>[a] Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.</u>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Symvenu 1.5mg Hard Capsules [Cariprazine hydrochloride 1.645mg (equivalent to 1.5 mg free base)] Symvenu 3mg Hard Capsules [Cariprazine hydrochloride 3.270mg (equivalent to 3 mg free base)] Symvenu 4.5mg Hard Capsules [Cariprazine hydrochloride 4.905 mg (equivalent to 4.5 mg free base)] Symvenu 6mg Hard Capsules [Cariprazine hydrochloride 6.540 mg (equivalent to 6 mg free base)]	**INDICATION :** Symvenu is indicated for - acute treatment of manic or mixed episodes associated with bipolar I disorder in adult patients. **POSOLOGY :** Manic or mixed episodes associated with Bipolar I Disorder The recommended dosage range is 3 mg to 6 mg once daily. The starting dose of cariprazine is 1.5 mg and should be increased to 3 mg on Day 2. Depending upon clinical response and tolerability, further dose adjustments can be made in 1.5 mg or 3 mg increments. The maximum recommended dosage is 6 mg daily. In short-term controlled trials, dosage above 6 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions.	**MITSUBISHI TANABE PHARMA MALAYSIA SDN. BHD.** Suite 8.3, Level 8, Wisma UOA Damansara II, No. 6, Changkat Semantan, 50490 Bukit Damansara, Wilayah Persekutuan Kuala Lumpur.