Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 415, 4 Disember 2025

Products approved for additional indication (DCA 415 – 4 Disember 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	BRUKINSA 80 mg capsules [Zanubrutinib 80mg]	**INDICATION :** BRUKINSA as monotherapy is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy This indication is approved based on overall response rate. Continued approval for this indication is contingent upon verification and description of clinical benefit in a confirmatory trial.	**BEIGENE MALAYSIA SDN. BHD.** Anchor Office 4, Level 4, Uptown 7, Jalan SS21/39, Damansara Utama, 47400 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>2.</td><td>XPOVIO 20mg Film-Coated Tablet

[Selinexor 20 mg]</td><td>
INDICATION :

XPOVIO is indicated:

• For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy who are not eligible for haematopoietic cell transplant.

This indication is approved based on the response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

POSOLOGY :

Treatment must be initiated and monitored under supervision of physicians experienced in the management of multiple myeloma and diffuse large B-cell lymphoma.

<u>Selinexor dosage for Diffuse Large B-Cell Lymphoma</u>

<u>The recommended dosage of selinexor is 60 mg taken orally on Days 1 and 3 of each week until disease progression or unacceptable toxicity.</u>

<u>Dose modifications</u>

Table 1: Prespecified dose modification steps for adverse reactions
<table>
<tr><th></th><th>Selinexor in combination with Bortezomib and Dexamethasone (SVd)</th><th>Selinexor in combination with Dexamethasone (Sd)</th><th>Selinexor for Diffuse Large B-cell Lymphoma DLBCL</th></tr>
</table>
</td><td>DKSH MALAYSIA SDN. BHD.
B-11-01, The Ascent, Paradigm,
No. 1, Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor.</td></tr>
</table>

<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>
<table>
<tr><td>Recommended starting dose</td><td>100 mg once weekly</td><td>80 mg Days 1 and 3 of each week (160 mg total per week)</td><td>60 mg Days 1 and 3 of each week (120 mg total per week)</td></tr>
<tr><td>First reduction</td><td>80 mg once weekly</td><td>100 mg once weekly</td><td>40 mg Days 1 and 3 of each week (80 mg total per week)</td></tr>
<tr><td>Second reduction</td><td>60 mg once weekly</td><td>80 mg once weekly</td><td>60 mg once weekly</td></tr>
<tr><td>Third reduction</td><td>40 mg once weekly</td><td>60 mg once weekly</td><td>40 mg once weekly</td></tr>
<tr><td colspan="4">Discontinue*</td></tr>
</table>
* If symptoms do not resolve, treatment should be discontinued

Recommended dosage modifications for haematologic adverse reactions in patients with multiple myeloma and DLBCL are presented in Table 2 and Table 3, respectively. Recommended dosage modifications for non-haematologic adverse reactions are presented in Table 4.

Table 2: Dose modification guidelines for Haematologic Adverse Reactions in Patients with Multiple Myeloma
<table>
<tr><th>Adverse Reaction[a]</th><th>Occurrence</th><th>Action</th></tr>
<tr><td colspan="3">Haematologic adverse reactions</td></tr>
<tr><td colspan="3">Thrombocytopaenia</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Platelet count 25,000 to less than 75,000/mcL	Any	• Reduce XPOVIO by 1 dose level (see **Table 1**).	
		Platelet count 25,000 to less than 75,000/mcL with concurrent bleeding	Any	• Interrupt XPOVIO. • Restart XPOVIO at 1 dose level lower (see **Table 1**), after bleeding has resolved.	
		Platelet count less than 25,000/mcL	Any	• Interrupt XPOVIO. • Monitor until platelet count returns to at least 50,000/mcL. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Neutropaenia			
		Absolute neutrophil count of 0.5 to 1.0 x 10^9 /L without fever	Any	• Reduce XPOVIO by 1 dose level (see **Table 1**).	
		Absolute neutrophil count less than 0.5 x 10^9 /L OR Febrile neutropaenia	Any	• Interrupt XPOVIO. • Monitor until neutrophil counts return to 1.0 x 10^9 /L or higher. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Anaemia			

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

Haemoglobin less than 8.0 g/dL	Any	• Reduce XPOVIO by 1 dose level (see **Table 1**). • Administer blood transfusions and/or other treatments per clinical guidelines.
Life-threatening consequences (urgent intervention indicated)	Any	• Interrupt XPOVIO. • Monitor haemoglobin until levels return to 8 g/dL or higher. • Restart XPOVIO at 1 dose level lower (see **Table 1**). • Administer blood transfusions and/or other treatments per clinical guidelines.

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

Table 3: Dose Modification Guidelines for Haematologic Adverse Reactions in Patients with Diffuse Large B-Cell Lymphoma

Adverse Reaction	Occurrence	Action
Haematologic adverse reactions		
Thrombocytopaenia		
Platelet count 50,000 to less than 75,000/mcL	Any	• Interrupt one dose of XPOVIO. • Restart XPOVIO at the same dose level.

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Platelet count 25,000 to less than 50,000/mcL without bleeding	Any	• Interrupt XPOVIO. • Monitor until platelet count returns to at least 50,000/mcL. • Reduce XPOVIO by 1 dose level (see **Table 1**).	
		Platelet count 25,000 to less than 50,000/mcL with concurrent bleeding	Any	• Interrupt XPOVIO. • Monitor until platelet count returns to at least 50,000/mcL. • Restart XPOVIO at 1 dose level lower (see **Table 1**), after bleeding has resolved. • Administer platelet transfusions per clinical guidelines.	
		Platelet count less than 25,000/mcL	Any	• Interrupt XPOVIO. • Monitor until platelet count returns to at least 50,000/mcL. • Restart XPOVIO at 1 dose level lower (see **Table 1**). • Administer platelet transfusions per clinical guidelines	
		Neutropaenia			
		Absolute neutrophil count of 0.5 to 1.0 x 10^9 /L without fever	1st occurrence	• Interrupt XPOVIO. • Monitor until neutrophil counts return to 1 x 10^9 /L or higher. • Restart XPOVIO at the same dose level.	

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
			Recurrence	• Interrupt XPOVIO. • Monitor until neutrophil counts return to 1 x 10^9 /L or higher. • Administer growth factors per clinical guidelines. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Absolute neutrophil count less than 0.5 x 10^9 /L OR Febrile neutropenia	Any	• Interrupt XPOVIO. • Monitor until neutrophil counts return to 1 x 10^9 /L or higher. • Administer growth factors per clinical guidelines. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Anaemia			
		Haemoglobin less than 8.0 g/dL	Any	• Reduce XPOVIO by 1 dose level (see **Table 1**). • Administer blood transfusions per clinical guidelines.	
		Life-threatening consequences (urgent intervention indicated)	Any	• Interrupt XPOVIO. • Monitor hemoglobin until levels return to 8 g/dL or higher. • Restart XPOVIO at 1 dose level lower (see **Table 1**). • Administer blood transfusions per clinical guidelines	

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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>
Table 4: Dose Modification Guidelines for Adverse Reactions
<table>
<tr><th>Adverse Reaction[a]</th><th>Occurrence</th><th>Action</th></tr>
<tr><td colspan="3">Non-haematologic adverse reactions</td></tr>
<tr><td colspan="3">Hyponatraemia</td></tr>
<tr><td>Sodium level 130 mmol/L or less</td><td>Any</td><td>• Interrupt XPOVIO and provide appropriate supportive care.
• Monitor until sodium levels return to 130 mmol/L or higher.
• Restart XPOVIO at 1 dose level lower (see Table 1).</td></tr>
<tr><td colspan="3">Fatigue</td></tr>
<tr><td>Grade 2 lasting greater than 7 days

OR

Grade 3</td><td>Any</td><td>• Interrupt XPOVIO.
• Monitor until fatigue resolves to Grade 1 or baseline.
• Restart XPOVIO at 1 dose level lower (see Table 1).</td></tr>
<tr><td colspan="3">Nausea and vomiting</td></tr>
</table>
</td><td></td></tr>
</table>

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Products approved for additional indication (DCA 415 – 4 Disember 2025)

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Grade 1 or 2 nausea (oral intake decreased without significant weight loss, dehydration or malnutrition) OR Grade 1 or 2 vomiting (5 or fewer episodes per day)	Any	• Maintain XPOVIO and initiate additional anti-nausea medicinal products.	
		Grade 3 nausea (inadequate oral caloric or fluid intake) OR Grade 3 or higher vomiting (6 or more episodes per day)	Any	• Interrupt XPOVIO. • Monitor until nausea or vomiting has resolved to Grade 2 or lower or baseline. • Initiate additional anti-nausea medicinal products. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Diarrhoea			
		Grade 2 (increase of 4 to 6 stools per day over baseline)	1st	• Maintain XPOVIO and institute supportive care.	
			2nd and subsequent	• Reduce XPOVIO by 1 dose level (see **Table 1**). • Institute supportive care.	

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Grade 3 or higher (increase of 7 stools or more per day over baseline; hospitalisation indicated)	Any	• Interrupt XPOVIO and institute supportive care. • Monitor until diarrhoea resolves to Grade 2 or lower. • Restart XPOVIO r at 1 dose level lower (see **Table 1**).	
		Weight loss and anorexia			
		Weight loss of 10% to less than 20% OR Anorexia associated with significant weight loss or malnutrition	Any	• Interrupt XPOVIO and institute supportive care. • Monitor until weight returns to more than 90% of baseline weight. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Ocular adverse reactions			
		Grade 2, excluding cataract	Any	• Perform ophthalmologic evaluation. • Interrupt XPOVIO and provide supportive care. • Monitor until ocular symptoms resolve to Grade 1 or baseline. • Restart XPOVIO at 1 dose level lower (see **Table 1**).	
		Grade ≥3, excluding cataract	Any	• Permanently discontinue XPOVIO. • Perform ophthalmologic evaluation.	
		Other non-haematologic adverse reactions			

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

Grade 3 or 4 (life threatening)		• Interrupt XPOVIO. • Monitor until resolved to Grade 2 or lower. • Restart XPOVIO at 1 dose level lower (see **Table 1**).

[a]National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

Special populations

Paediatric population

The safety and efficacy of XPOVIO in children below the age of 18 years of age have not been established. No data are available. There is no relevant use of XPOVIO in children less than 18 years of age in the treatment of multiple myeloma and diffuse large B-cell lymphoma.

Method of administration

XPOVIO as a monotherapy in DLBCL indication should be taken orally at approximately the same time on Days 1 and 3 of each week.

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Products approved for additional indication (DCA 415 – 4 Disember 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	CALQUENCE 100MG FILM-COATED TABLET [Acalabrutinib maleate 100mg]	**INDICATION :** Calquence in combination with venetoclax with or without obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). **POSOLOGY :** The recommended dose of Calquence in monotherapy or in combination with other medicinal products is 100 mg acalabrutinib twice daily (equivalent to a total daily dose of 200 mg). Calquence dose interval is approximately 12 hours. For the combination regimens, refer to the prescribing information of each of the medicinal product for their dosing information (for details of the combination regimens, see section 5.1). Calquence in combination with venetoclax with or without obinutuzumab Treatment with Calquence in combination with venetoclax with or without obinutuzumab, should continue until disease progression, unacceptable toxicity or completion of 14 cycles of treatment (each cycle is 28 days). Calquence should be administered on Day 1 of Cycle 1 for a total of 14 cycles. Venetoclax should be administered on Day 1 of Cycle 3 for a total of 12 cycles, starting at 20 mg and increasing weekly to 50 mg, 100 mg, 200 mg and finally 400 mg. If Calquence is given in combination with venetoclax and obinutuzumab, obinutuzumab should be administered at 100 mg on Day 1 of Cycle 2, followed by 900 mg which may be administered on Day 1 or 2. Administer obinutuzumab at 1 000 mg on Day 8 and 15 of Cycle 2, followed by 1 000 mg on Day 1 of Cycles 3 to 7. Obinutuzumab is administered for a total of 6 cycles.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Beyfortus solution for injection in pre-filled syringe 50 mg/ 0.5 mL Beyfortus solution for injection in pre-filled syringe 100 mg/ 1.0 mL [Nirsevimab 100 mg/ml]	**INDICATION :** Beyfortus is indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season (see section Pharmacodynamic Properties). **POSOLOGY :** ***Children who remain vulnerable to severe RSV disease through their second RSV season*** *The recommended dose is a single dose of 200 mg given as two intramuscular injections (2 x 100 mg).* *Beyfortus should be administered ideally prior to the start of the second RSV season.* *For individuals undergoing cardiac surgery with cardiopulmonary bypass, an additional dose may be administered as soon as the individual is stable after surgery to ensure adequate nirsevimab serum levels. If within 90 days after receiving the first dose of Beyfortus, the additional dose during the first RSV season should be 50 mg or 100 mg according to body weight, or 200 mg during the second RSV season. If more than 90 days have elapsed since the first dose, the additional dose could be a single dose of 50 mg regardless of body weight during the first RSV season, or 100 mg during the second RSV season, to cover the remainder of the RSV season.* *The safety and efficacy of nirsevimab in children aged 2 to 18 years have not been established. No data are available.*	**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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<tr><td>5.</td><td>IMFINZI CONCENTRATE FOR SOLUTION FOR INTRAVENOUS INFUSION 50 MG/ML

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

<u>Small Cell Lung Cancer (SCLC)</u>

IMFINZI as monotherapy is indicated for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

POSOLOGY :

Recommended dosage of Imfinzi:

<table>
<tr><th>Indication</th><th>Recommended IMFINZI dosage</th><th>Duration of Therapy</th></tr>
<tr><td>LS-SCLC</td><td>Patients with a body weight of more than 30 kg: 1500 mg every 4 weeks

Patients with a body weight of 30 kg or less: 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.</td><td>Until disease progression, unacceptable toxicity, or a maximum of 24 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>