Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 419, 2 April 2026

Products approved for additional indication (DCA 419 – 2 April 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Calquence 100mg Film-Coated Tablet [Acalabrutinib maleate 129mg (equivalent to 100mg of acalabrutinib)]	**INDICATION:** Calquence in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are not eligible for autologous stem cell transplant (ASCT). Calquence as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) not previously treated with a BTK inhibitor. **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 bendamustine and rituximab Calquence should be administered on Day 1 on Cycle 1 (each cycle is 28 days) until disease progression or unacceptable toxicity. Bendamustine should be administered at 90 mg/m2 on Days 1 and 2 of each cycle for a total of 6 cycles. Rituximab should be administered at 375 mg/m2 on Day 1 each cycle for a total of 6 cycles. Patients achieving a response (partial response [PR] or complete response [CR]) after the first 6 cycles, may receive maintenance rituximab at 375 mg/m2 on Day 1 of every other cycle for a maximum of 12 additional doses, starting on Cycle 8 up to Cycle 30.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800, Petaling Jaya Selangor.

<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>
<u>Dose adjustments</u>

Adverse reactions

Recommended dose modifications for Grade ≥ 3 adverse reactions in patients receiving Calquence in combination with bendamustine and rituximab are provided in Table 2.

Table 2. Recommended dose adjustments for Grade ≥ 3 adverse reactions* in patients receiving Calquence in combination with bendamustine and rituximab
<table>
<tr><th>Adverse reaction</th><th>Bendamustine dose modification†</th><th>Calquence dose modification</th></tr>
<tr><td>Neutropenia</td><td>If Grade 3 or Grade 4 neutropenia‡:
Interrupt bendamustine.
Once toxicity has resolved to Grade ≤ 2 or baseline level, bendamustine may be resumed at 70 mg/m^2.
Discontinue bendamustine if additional dose reduction is required.</td><td>If Grade 4 neutropenia lasting longer than 7 days then interrupt Calquence.
Once toxicity has resolved to Grade ≤ 2 or baseline level, Calquence may be resumed at starting dose (1st adverse reaction occurrence) or at a reduced frequency of 100 mg once daily (2nd and 3rd adverse reaction occurrence).¶
Discontinue Calquence at 4th adverse reaction occurrence.</td></tr>
</table>
</td><td></td></tr>
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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Thrombocytopenia	If Grade 3 or Grade 4 thrombocytopenia: Interrupt bendamustine. Once toxicity has resolved to Grade ≤ 2 or baseline level, bendamustine may be resumed at 70 mg/m^2. Discontinue bendamustine if additional dose reduction is required.	If Grade 3 thrombocytopenia with significant bleeding or Grade 4 then interrupt Calquence. Once toxicity has resolved to Grade ≤ 2 or baseline level, Calquence may be resumed at starting dose (1st adverse reaction occurrence) or at a reduced frequency of 100 mg once daily (2nd and 3rd occurrence).¶ Discontinue Calquence at 3rd adverse reaction occurrence for thrombocytopenia with significant bleeding. Discontinue Calquence at 4th adverse reaction occurrence.	
		Other hematologic Grade 4§ or unmanageable Grade 3 toxicity	Interrupt bendamustine. Once toxicity has resolved to Grade ≤ 2 or baseline level, bendamustine may be resumed at 70 mg/m^2. Discontinue bendamustine if additional dose reduction is	Interrupt Calquence. Once toxicity has resolved to Grade ≤ 2 or baseline level, Calquence may be resumed at starting dose (1st adverse reaction occurrence) or at a reduced frequency of 100 mg once daily (2nd and 3rd adverse	

No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
			required.	reaction occurrence).¶ Discontinue Calquence at 4th adverse reaction occurrence.	
		Grade 3 or greater non-hematologic toxicities	Interrupt bendamustine. Once toxicity has resolved to Grade 1 or baseline level, bendamustine may be resumed at 70 mg/m^2. Discontinue bendamustine if additional dose reduction is required.	Interrupt Calquence. Once toxicity has resolved to Grade 2 or baseline, Calquence may be resumed at starting dose (1st adverse reaction occurrence) or at a reduced frequency of 100 mg once daily (2nd adverse reaction occurrence).¶ Discontinue Calquence at 3rd adverse reaction occurrence.	

*Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.
†For any toxicities not listed in this table refer to the bendamustine local prescribing information.
‡Consider use of myeloid growth factors before bendamustine dose modifications.
§Grade 4 lymphopenia is an expected outcome for treatment with bendamustine and rituximab. Dose modification due to lymphopenia is expected only if considered clinically important by investigators e.g. associated recurrent infections.
¶Dose may be re-escalated at the discretion of the physician if patient tolerates a reduced dose for ≥4 weeks.

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Products approved for additional indication (DCA 419 – 2 April 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Adcetris 50mg, powder for concentrate for solution for infusion [Brentuximab vedotin 50mg]	**INDICATION:** ADCETRIS is indicated for adult patients with previously untreated CD30+ Stage IIB with risk factors, Stage III or Stage IV HL in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone (BrECADD). **POSOLOGY:** BrECADD The recommended dose in combination with chemotherapy (etoposide (E), cyclophosphamide (C), doxorubicin (A), dacarbazine (D), dexamethasone (D) [BrECADD]) is 1.8 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks for up to 6 cycles (see section Clinical Studies). Primary prophylaxis with growth factor support (G-CSF) must be given beginning on day 5 of each cycle for all adult patients with previously untreated HL receiving combination therapy (see section Warnings and Precautions). Pretreatment with dexamethasone for 4 days before the first cycle of chemotherapy is recommended for patients > 40 years of age or at physician's discretion. An antibiotic prophylaxis must be given 3 x/week during the whole duration of chemotherapy. Refer to Table 4 for dosing recommendations for chemotherapy agents given in combination with ADCETRIS for patients with previously untreated HL.	**TAKEDA MALAYSIA SDN BHD** Unit TB-L13-1, Level 13 Tower B, Plaza 33 No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor

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<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>3.</td><td>Imfinzi Concentrate for Solution for Intravenous Infusion 50 mg/ml

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

<u>Muscle Invasive Bladder Cancer (MIBC)</u>

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC).

POSOLOGY:
<table>
<tr><th>Indication</th><th>Recommended IMFINZI dosage</th><th>Duration of Therapy</th></tr>
<tr><td>MIBC</td><td>Patients with body weight of more than 30 kg:
Neoadjuvant: 1500 mg in combination with gemcitabine and cisplatin[a] every 3 weeks for 4 cycles prior to surgery
Adjuvant: IMFINZI 1500 mg as a single agent every 4 weeks for up to 8 cycles after surgery

Patients with body weight of 30 kg or less:
Neoadjuvant: 20 mg/kg in combination with gemcitabine and cisplatin[a] every 3 weeks for 4 cycles prior to surgery

Adjuvant: IMFINZI 20 mg/kg as a single agent every 4 weeks for up to 8 cycles after surgery</td><td>Until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity or a maximum of 8 cycles after surgery</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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Products approved for additional indication (DCA 419 – 2 April 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Opdivo 10mg/ml, Concentrate for solution for infusion [Nivolumab 10mg/ml]	**INDICATION:** <u>Neoadjuvant and adjuvant treatment of NSCLC</u> OPDIVO, in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by OPDIVO as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1% (see section 5.1 for selection criteria). **POSOLOGY:** <u>*Neoadjuvant and adjuvant 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 4 cycles in the neoadjuvant phase, followed by adjuvant treatment with nivolumab 480 mg as monotherapy every 4 weeks. Treatment is recommended until disease progression or recurrence, unacceptable toxicity, or up to 13 cycles (see section 5.1).	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya**,** 47301 Petaling Jaya**,** Selangor.