Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 414, 3 November 2025

Products approved for additional indication (DCA 414 – 3 November 2025)

<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>Zavicefta (Ceftazidime 2g/Avibactam 0.5g) Powder for Concentrate for Solution for Infusion

[Ceftazidime Pentahydrate 2360.7mg (equivalent to 2000mg of Ceftazidime) / Avibactam Sodium 550.7mg (equivalent to 500mg of Avibactam)]</td><td>INDICATION :

Zavicefta is indicated in adults and paediatric patients from birth for the treatment of the following infections:

• Complicated intra-abdominal infection (cIAI), in combination with metronidazole.
• Complicated urinary tract infection (cUTI), including pyelonephritis.

POSOLOGY :

Table 3: Recommended dose for paediatric patients less than 3 months of age[8]
<table>
<tr><th>Type of infection</th><th>Age group</th><th></th><th>Dose of ceftazidime/ avibactam[4]</th><th>Frequency</th><th>Infusion time</th><th>Duration of treatment</th></tr>
<tr><td rowspan="3">cIAI[1,2]
OR
cUTI, including pyelonephritis[3]</td><td rowspan="2">Full term neonates and infants</td><td>>28 days to <3 months</td><td>30 mg/kg/7.5 mg/kg</td><td rowspan="2">Every 8 hours</td><td rowspan="2">2 hours</td><td rowspan="3">cIAI: 5 – 14 days

cUTI[3]: 5 – 14 days</td></tr>
<tr><td>Birth to ≤28 days</td><td>20 mg/kg/5 mg/kg</td></tr>
<tr><td>Preterm neonates and infants[5]</td><td>>44 weeks to <53 weeks PMA[6]</td><td>30 mg/kg/7.5 mg/kg</td><td>Every 8 hours</td><td>2 hours</td></tr>
<tr><td></td><td></td><td>31 to</td><td>20 mg/kg/5</td><td></td><td></td><td></td></tr>
</table>
</td><td>PFIZER (MALAYSIA) SDN. BHD.
Level 10 & 11, Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No.8, Jalan Kerinchi,
59200 Kuala Lumpur,
Wilayah Persekutuan
Kuala Lumpur.</td></tr>
</table>

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

		≤44 weeks PMA[6]	mg/kg			
		26 to <31 weeks PMA[6,7]	20 mg/kg/5 mg/kg	Every 12 hours	2 hours	

[1] To be used in combination with metronidazole when anaerobic pathogens are known or suspected to be contributing to the infectious process.

[2] To be used in combination with an antibacterial agent active against Gram-positive pathogens when these are known or suspected to be contributing to the infectious process

[3] The total treatment duration shown may include intravenous Zavicefta followed by appropriate oral therapy.

[4] Ceftazidime/avibactam is a combination product in a fixed 4:1 ratio and dosage recommendations are based on the ceftazidime component only (see section 6.6 Instructions for use, handling and disposal).

[5] Preterm defined as < 37 weeks gestation.

[6] Postmenstrual age.

[7] Dose recommendations for patients 26 to < 31 weeks PMA are based on pharmacokinetic modelling only (see section 5.2 Pharmacokinetic Properties).

[8] Patients with serum creatinine at or below the upper limit of normal for age.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	LUMAKRAS FILM-COATED TABLET 120MG [Sotorasib 120 mg]	**INDICATION :** 1.2 KRAS G12C-mutated Metastatic Colorectal Cancer (mCRC) LUMAKRAS, in combination with panitumumab, is indicated for the treatment of adult patients with KRAS G12C-mutated metastatic colorectal cancer (mCRC), who have received prior fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy. **POSOLOGY :** **2.1 Patient Selection** <u>KRAS G12C-mutated mCRC</u> Select patients for treatment of mCRC based on the presence of KRAS G12C mutation in tumor specimens [see Clinical Studies (14.2)]. **2.2 Recommended Dosage and Administration** **LUMAKRAS in Combination with Panitumumab for KRAS G12C-mutated mCRC** The recommended dosage of LUMAKRAS is 960 mg (eight 120 mg tablets) orally once daily in combination with panitumumab until disease progression or unacceptable toxicity. Administer the first dose of LUMAKRAS prior to first panitumumab infusion. Refer to the panitumumab full prescribing information for recommended panitumumab dosage information. <u>Administration to Patients Who Have Difficulty Swallowing Solids</u> Disperse tablets in 120 mL (4 ounces) of non-carbonated, room-temperature water without crushing. No other liquids should be used. Stir or swirl the cup for approximately 3 minutes until tablets are dispersed into small pieces (the tablets will not completely dissolve) and drink immediately or within 2 hours. The appearance of the mixture may range from pale yellow to	**AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD** Common Ground, 1 Powerhouse, Horizon Penthouse, No. 1, Persiaran Bandar Utama, Bandar Utama, 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>
bright yellow. Swallow the tablet dispersion. Do not chew pieces of the tablet. Rinse the container with an additional 120 mL (4 ounces) of water and drink. If the mixture is not consumed immediately, stir the mixture again to ensure that tablets are dispersed.

If administration through a nasogastric (NG) tube or percutaneous endoscopic gastrostomy (PEG) tube is required, follow the process above for the initial dispersion and for the residual rinse of the 120 mg tablets. The resulting dispersed suspension and rinse should be administered as per the NG or PEG tube manufacturer's instructions with appropriate water flushes. Administer within two hours of preparation, stored at room temperature.

2.3 Dosage Modifications for Adverse Reactions

When LUMAKRAS is administered in combination with panitumumab, and LUMAKRAS is temporarily withheld or permanently discontinued, temporarily withhold or permanently discontinue panitumumab, respectively [see Clinical Studies (14.2)]. Refer to the full prescribing information of panitumumab for dose modifications for adverse reactions associated with the use of panitumumab.

Treatment with LUMAKRAS as a single agent may be continued if panitumumab is permanently discontinued [see Clinical Pharmacology (12.1), Clinical Studies (14.2)].

Refer to Table 2 for dose modification guidelines and management of adverse reactions associated with the use of LUMAKRAS as a single agent or as combination therapy with panitumumab.

Table 2. Recommended LUMAKRAS Dosage Modifications for Adverse Reactions
<table>
<tr><th>Adverse Reaction</th><th>Severity[a]</th><th>Dosage Modification[b]</th></tr>
<tr><td>Hepatotoxicity [see Warnings and Precautions (5.1)]</td><td>AST or ALT > 3 x and up to 5 x ULN (or > 3 x and up to 5 x baseline abnormal) with symptoms</td><td>• Withhold LUMAKRAS until recovery to ≤ 3 x ULN or to < 3 x baseline if baseline abnormal.
• Resume LUMAKRAS at the next lower dose level.</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
			or AST or ALT > 5 x ULN (or > 5 x baseline if baseline abnormal)		
			AST or ALT > 3 × ULN with total bilirubin > 2 × ULN	• Permanently discontinue LUMAKRAS if no alternative cause is identified. • If alternative cause is identified, do not resume LUMAKRAS until AST/ALT/bilirubin return to baseline.	
		Interstitial Lung Disease (ILD)/ pneumonitis [see Warnings and Precautions (5.2)]	Any Grade	• Withhold LUMAKRAS if ILD/pneumonitis is suspected. • Permanently discontinue LUMAKRAS if ILD/pneumonitis is confirmed.	
		Nausea or vomiting despite appropriate supportive care (including anti-emetic therapy) [see Adverse Reactions (6.1)]	Grade 3 to 4	• Withhold LUMAKRAS until recovery to ≤ Grade 1 or baseline. • Resume LUMAKRAS at the next lower dose level.	

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

Diarrhea despite appropriate supportive care (including anti-diarrheal therapy) [see Adverse Reactions (6.1)]	Grade 3 to 4	• Withhold LUMAKRAS until recovery to ≤ Grade 1 or baseline. • Resume LUMAKRAS at the next lower dose level.
Other adverse reactions [see Adverse Reactions (6.1)]	Grade 3 to 4	• Withhold LUMAKRAS until recovery to ≤ Grade 1 or baseline. • Resume LUMAKRAS at the next lower dose level.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; ULN = upper limit of normal

[a] Grading defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0

[b] When LUMAKRAS is administered in combination with panitumumab, withhold or permanently discontinue treatment with panitumumab when withholding or permanently discontinuing treatment with LUMAKRAS.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	RINVOQ 15mg Extended Release Film Coated Tablets [Upadacitinib Hemihydrate 15.4mg (Corresponds to 15 mg of upadacitinib)]	**INDICATION :** Giant cell arteritis RINVOQ is indicated for the treatment of giant cell arteritis in adult patients. **POSOLOGY :** Giant cell arteritis The recommended dose of upadacitinib is 15 mg once daily in combination with a tapering course of corticosteroids. Upadacitinib monotherapy should not be used for the treatment of acute relapses (see section Special warnings and precautions for use). Based upon the chronic nature of giant cell arteritis, upadacitinib 15 mg once daily can be continued as monotherapy following discontinuation of corticosteroids. Treatment beyond 52 weeks should be guided by disease activity, physician discretion, and patient choice.	**ABBVIE SDN BHD** 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Tevimbra 100mg/ 10 ml Concentrate for Solution for Infusion [Tislelizumab 100 mg/10 ml]	**INDICATION :** Non-small cell lung cancer (NSCLC) Tevimbra in combination with pemetrexed and platinum-containing chemotherapy is indicated for the first-line treatment of adult patients with non-squamous NSCLC whose tumours have PD-L1 expression on ≥50% of tumour cells with no EGFR or ALK positive mutations and who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC. Tevimbra in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of adult patients with squamous NSCLC who have: • locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or • metastatic NSCLC. Tevimbra as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior platinum-based therapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving tislelizumab. **POSOLOGY :** <u>Tevimbra monotherapy</u> The recommended dose of Tevimbra is 200 mg administered by intravenous infusion once every 3 weeks.	**BEIGENE MALAYSIA SDN. BHD.** Anchor Office 4, Level 4, Uptown 7, Jalan SS21/39, Damansara Utama, 47400 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Tevimbra combination therapy The recommended dose of Tevimbra is 200 mg administered by intravenous infusion once every 3 weeks, in combination with chemotherapy. When Tevimbra and chemotherapy are administered on the same day, Tevimbra should be administered before chemotherapy. The package insert for the chemotherapy product should be referred to for dosing as well as for recommendations on corticosteroid use as pre-medication for the prevention of chemotherapy-related adverse reactions. Duration of treatment Patients should be treated with Tevimbra until disease progression or unacceptable toxicity. Dose delay or discontinuation (see also section 4.4) No dose reductions of Tevimbra as monotherapy or in combination therapy are recommended. Tevimbra should be withheld or discontinued as described in Table 1.	

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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>5.</td><td>COLUMVI 1mg/mL Concentrate for Solution for Infusion

[Glofitamab 1mg/ml]</td><td>
INDICATION :

Columvi in combination with gemcitabine and oxaliplatin is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT).

POSOLOGY :

Columvi dose step-up schedule in combination with gemcitabine and oxaliplatin

Columvi must be administered as an intravenous infusion according to the dose step-up schedule leading to the recommended dose of 30 mg (as shown in Table 3), after completion of pre-treatment with obinutuzumab on Cycle 1 Day 1.

Columvi is given in combination with gemcitabine and oxaliplatin at Cycles 1-8 and as monotherapy at Cycles 9-12. Each cycle is 21 days.

Table 3 Columvi dose step-up schedule in combination with gemcitabine and oxaliplatin for patients with relapsed or refractory DLBCL
<table>
<tr><th colspan="2">Treatment cycle, Day</th><th>Dose of Columvi (duration of infusion)</th><th>Dose of gemcitabine</th><th>Dose of oxaliplatin</th></tr>
<tr><td rowspan="4">Cycle 1 (Pre-treatment and step-up dose)</td><td>Day 1</td><td colspan="3">Pre-treatment with obinutuzumab 1000 mg[a]</td></tr>
<tr><td>Day 2</td><td>–</td><td>1000 mg/m^{2} [b]</td><td>100 mg/m^{2} [b]</td></tr>
<tr><td>Day 8</td><td>2.5 mg (4 hours)[c]</td><td rowspan="2">–</td><td rowspan="2">–</td></tr>
<tr><td>Day 15</td><td>10 mg (4 hours)[c]</td></tr>
<tr><td>Cycle 2</td><td>Day 1</td><td>30 mg (4 hours)[c,d]</td><td>1000 mg/m^{2} [b,d]</td><td>100 mg/m^{2} [b,d]</td></tr>
</table>
</td><td>ROCHE (MALAYSIA) SDN. BHD.
Level 21, The Pinnacle,
Persiaran Lagoon,
Bandar Sunway,
47500 Subang Jaya,
Selangor.</td></tr>
</table>

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

Cycle 3 to 8	Day 1	30 mg (2 hours)[d,e]	1000 mg/m^2 [b,d]	100 mg/m^2 [b,d]
Cycle 9 to 12	Day 1	30 mg (2 hours)[e]	–	–

[a] Refer to “Pre-treatment with obinutuzumab” described above.

[b] Cycles 1-8: Administer gemcitabine before oxaliplatin.

[c] For patients who experience CRS with their previous dose of Columvi, the time of infusion may be extended up to 8 hours (see section 2.4).

[d] Cycles 2-8: Administer Columvi before gemcitabine and oxaliplatin. Gemcitabine and oxaliplatin may be given on Day 1 or 2.

[e] Infusion time may be shortened to 2 hours at the discretion of the treating physician, if the previous infusion was well tolerated. If the patient experienced CRS with a previous dose, the duration of infusion should be maintained at 4 hours.

<u>Monitoring after infusion</u>

- When Columvi is given as monotherapy, patients must be monitored for signs and symptoms of potential CRS during all Columvi infusions and for at least 10 hours after completion of the infusion of the first Columvi dose (2.5 mg on Cycle 1 Day 8) (see section 2.6).
- When Columvi is given in combination with gemcitabine and oxaliplatin, patients must be monitored for signs and symptoms of potential CRS during all Columvi infusions and for 4 hours after completion of the first Columvi dose (2.5 mg on Cycle 1 Day 8) (see section 2.6).

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Patients who experienced Grade 2 CRS with their previous infusion should be monitored after completion of the infusion (see Table 4 in section 2.2). All patients must be monitored for signs and symptoms of CRS and immune effector cell-associated neurotoxicity syndrome (ICANS) following Columvi administration. All patients must be counselled on the risk, signs and symptoms of CRS and ICANS and advised to contact the healthcare provider immediately should they experience signs and symptoms of CRS and/or ICANS at any time (see section 2.4). Duration of Treatment Treatment with Columvi monotherapy is recommended for a maximum of 12 cycles or until disease progression or unmanageable toxicity, whichever occurs first. Each cycle is 21 days. Treatment with Columvi in combination with gemcitabine and oxaliplatin is recommended for 8 cycles, followed by 4 cycles of Columvi monotherapy for a maximum of 12 cycles of Columvi in total or until disease progression or unmanageable toxicity, whichever occurs first. Each cycle is 21 days.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	YERVOY 5 mg/ml concentrate for solution for infusion [Ipilimumab 5mg/ml]	**INDICATION :** <u>Hepatocellular carcinoma (HCC)</u> YERVOY in combination with nivolumab is indicated for the first-line treatment of adult patients with unresectable or advanced hepatocellular carcinoma. **POSOLOGY :** Treatment must be initiated and supervised by specialist physicians experienced in the treatment of cancer. <u>PD-L1 testing</u> If specified in the indication, patient selection for treatment with YERVOY 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> YERVOY in combination with nivolumab Renal cell carcinoma The recommended dose is 1 mg/kg ipilimumab in combination with 3 mg/kg nivolumab administered intravenously every 3 weeks for the first 4 doses. This is then followed by a second phase in which nivolumab monotherapy is administered intravenously at either 3 mg/kg every 2 weeks **or** 240 mg every 2 weeks **or** at 480 mg every 4 weeks, as presented in Table 1. For the monotherapy phase, the first dose of nivolumab should be administered; • 3 weeks after the last dose of the combination of ipilimumab and nivolumab if using 3 mg/kg every 2 weeks or 240 mg every 2 weeks; or • 6 weeks after the last dose of the combination of ipilimumab and nivolumab if using 480 mg every 4 weeks.	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 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>
Table 1: Recommended doses and infusion times for intravenous administration of ipilimumab in combination with nivolumab for RCC
<table>
<tr><td></td><td>Combination phase, every 3 weeks for 4 dosing cycles</td><td>Monotherapy phase</td></tr>
<tr><td>Nivolumab</td><td>3 mg/kg over 30 minutes</td><td>3 mg/kg every 2 weeks over 30 minutes
or
240 mg every 2 weeks over 30 minutes
or
480 mg every 4 weeks over 60 minutes</td></tr>
<tr><td>Ipilimumab</td><td>1 mg/kg over 30 minutes</td><td>-</td></tr>
</table>
Oesophageal squamous cell carcinoma

The recommended dose is 1 mg/kg ipilimumab administered intravenously over 30 minutes every 6 weeks in combination with either 3 mg/kg nivolumab every 2 weeks or 360 mg nivolumab every 3 weeks administered intravenously over 30 minutes. Treatment is recommended until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Hepatocellular carcinoma

The recommended dose is 3 mg/kg ipilimumab in combination with 1 mg/kg nivolumab administered intravenously every 3 weeks for up to 4 doses. This is then followed by a second phase in which nivolumab monotherapy is administered intravenously at either 240 mg every 2 weeks or at 480 mg every 4 weeks (see sections 5.1 and 5.2), as presented in Table 2. Treatment is recommended until disease progression, unacceptable toxicity, or up to 24 months. For the monotherapy phase, the first dose
</td><td></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>
of nivolumab should be administered:

• 3 weeks after the last dose of the combination of nivolumab and ipilimumab if using 240 mg every 2 weeks or 480 mg every4 weeks.
Table 2: Recommended doses and infusion times for intravenous administration of ipilimumab in combination with nivolumab for HCC
<table>
<tr><td></td><td>Combination phase, every 3 weeks for 4 dosing cycles</td><td>Monotherapy phase</td></tr>
<tr><td>Nivolumab</td><td>1 mg/kg over 30 minutes</td><td>240 mg every 2 weeks over 30 minutes or 480 mg every 4 weeks over 30 minutes</td></tr>
<tr><td>Ipilimumab</td><td>3 mg/kg over 30 minutes</td><td>-</td></tr>
</table>

YERVOY in combination with nivolumab and chemotherapy

Non-small cell lung cancer

The recommended dose is 1 mg/kg ipilimumab administered intravenously over 30 minutes every 6 weeks in combination with 360 mg nivolumab administered intravenously over 30 minutes every 3 weeks, and platinum-based chemotherapy administered every 3 weeks. After completion of 2 cycles of chemotherapy, treatment is continued with 1 mg/kg ipilimumab every 6 weeks in combination with 360 mg nivolumab administered intravenously every 3 weeks. Treatment is recommended until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
</td><td></td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Duration of treatment Treatment with YERVOY in combination with nivolumab, should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient. (and up to maximum duration of therapy if specified for an indication). Atypical responses (i.e., an initial transient increase in tumour size or small new lesions within the first few months followed by tumour shrinkage) have been observed. It is recommended to continue treatment with YERVOY in combination with nivolumab for clinically stable patients with initial evidence of disease progression until disease progression is confirmed. Liver function tests (LFTs) and thyroid function tests should be evaluated at baseline and before each dose of YERVOY. In addition, any signs or symptoms of immune-related adverse reactions, including diarrhoea and colitis, must be assessed during treatment with YERVOY (see section 4.4). Children younger than 18 years of age The safety and efficacy of ipilimumab in children younger than 18 years of age has not been established. <u>Permanent discontinuation of treatment or withholding of doses</u> Management of immune-related adverse reactions may require withholding of a dose or permanent discontinuation of YERVOY therapy and institution of systemic high-dose corticosteroid. In some cases, addition of other immunosuppressive therapy may be considered (see section 4.4). Dose escalation or reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability.	

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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>Guidelines for permanent discontinuation or withholding of doses are described in Table 3 for YERVOY in combination with nivolumab or administration of the second phase of treatment (nivolumab monotherapy) following combination treatment. Detailed guidelines for the management of immune-related adverse reactions are described in section 4.4.

Table 3: Recommended treatment modifications for YERVOY in combination with nivolumab or administration of the second phase of treatment (nivolumab monotherapy) following combination treatment

<table>
<tr><th>Immune-related adverse reaction</th><th>Severity</th><th>Treatment modification</th></tr>
<tr><td rowspan="2">Immune-related pneumonitis</td><td>Grade 2 pneumonitis</td><td>Withhold dose(s) until symptoms resolve, radiographic abnormalities improve, and management with corticosteroids is complete</td></tr>
<tr><td>Grade 3 or 4 pneumonitis</td><td>Permanently discontinue treatment</td></tr>
<tr><td rowspan="2">Immune-related colitis</td><td>Grade 2 diarrhoea or colitis</td><td>Withhold dose(s) until symptoms resolve and management with corticosteroids, if needed, is complete</td></tr>
<tr><td>Grade 3 or 4 diarrhoea or colitis</td><td>Permanently discontinue treatment</td></tr>
</table>
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		Immune-related hepatitis **without HCC**	Grade 2 elevation in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin	Withhold dose(s) until laboratory values return to baseline and management with corticosteroids, if needed, is complete	
			Grade 3 or 4 elevation in AST, ALT, or total bilirubin	Permanently discontinue treatment	
		Immune-related hepatitis with HCC	If AST/ALT is within normal limits at baseline and increases to > 3 and ≤ 10 times ULN or Baseline AST/ALT is > 1 and ≤3 times ULN and increases to > 5 and ≤10 times ULN or Baseline AST/ALT is > 3 and ≤5 times ULN and increases to > 8 and ≤10 times ULN	Withhold dose(s) until laboratory values return to baseline and management with corticosteroids, if needed, is complete	
			AST/ALT increases to > 10 times ULN or Total bilirubin increases to > 3 times ULN	Permanently discontinue treatment	
		Immune-related nephritis and renal	Grade 2 or 3 creatinine elevation	Withhold dose(s) until creatinine returns to baseline and management with corticosteroids is	

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No.	Product [Active Ingredient]	Additional Indication			Product Registration Holder (PRH)
		dysfunction		complete	
			Grade 4 creatinine elevation	Permanently discontinue treatment	
		Immune-related endocrinopathies	Symptomatic Grade 2 or 3 hypothyroidism, hyperthyroidism, hypophysitis, Grade 2 adrenal insufficiency Grade 3 diabetes	Withhold dose(s) until symptoms resolve and management with corticosteroids (if needed for symptoms of acute inflammation) is complete. Treatment should be continued in the presence of hormone replacement therapy[a] as long as no symptoms are present	
			Grade 4 hypothyroidism Grade 4 hyperthyroidism Grade 4 hypophysitis Grade 3 or 4 adrenal insufficiency Grade 4 diabetes	Permanently discontinue treatment	
		Immune-related skin adverse reactions	Grade 3 rash	Withhold dose(s) until symptoms resolve and management with corticosteroids is complete	
			Grade 4 rash	Permanently discontinue treatment	
			Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)	Permanently discontinue treatment (see section 4.4)	
		Immune-related	Grade 2 myocarditis	Withhold dose(s) until symptoms resolve and management with	

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

myocarditis | | corticosteroids is complete[b]

	Grade 3 or 4 myocarditis	Permanently discontinue treatment
Other immune-related adverse reactions	Grade 3 (first occurrence)	Withhold dose(s)
	Grade 4 or recurrent Grade 3 ; persistent Grade 2 or 3 despite treatment modification ; inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day	Permanently discontinue treatment

Note: Toxicity grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 (NCI-CTCAE v4).

[a] Recommendation for the use of hormone replacement therapy is provided in section 4.4.
[b] The safety of re-initiating ipilimumab in combination with nivolumab therapy in patients previously experiencing immune-related myocarditis is not known.

YERVOY in combination with nivolumab should be permanently discontinued for:

- Grade 4 or recurrent Grade 3 adverse reactions;
- Persistent Grade 2 or 3 adverse reactions despite management.

When YERVOY is administered in combination with nivolumab, if either agent is withheld, the other agent should also be withheld. If dosing is resumed after a delay, either the combination treatment or nivolumab monotherapy could be resumed based on the evaluation of the individual patient.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 414, 3 November 2025

Products approved for additional indication (DCA 414 – 3 November 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Special populations</u> Paediatric population The safety and efficacy of YERVOY in combination with nivolumab in children younger than 18 years of age have not been established. Currently available data are described in sections 4.8 and 5.1 but no recommendation on a posology can be made. Elderly No overall differences in safety or efficacy were reported between elderly (≥ 65 years) and younger patients (< 65 years). Data from first-line RCC patients 75 years of age or older are too limited to draw conclusions on this population (see section 5.1). No specific dose adjustment is necessary in this population (see section 5.1). Renal impairment The safety and efficacy of YERVOY have not been studied in patients with renal impairment. Based on population pharmacokinetic results, no specific dose adjustment is necessary in patients with mild to moderate renal dysfunction (see section 5.2). Hepatic impairment The safety and efficacy of YERVOY have not been studied in patients with hepatic impairment. Based on the population pharmacokinetic results, no specific dose adjustment is necessary in patients with mild hepatic impairment (see section 5.2). YERVOY must be administered with caution in patients with transaminase levels ≥ 5 x ULN or bilirubin levels > 3 x ULN at baseline (see section 5.1).	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 414, 3 November 2025

Products approved for additional indication (DCA 414 – 3 November 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Method of administration YERVOY is for intravenous use. The recommended infusion period is 30 minutes. YERVOY can be used for intravenous administration without dilution or may be diluted in sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection to concentrations between 1 and 4 mg/ml. YERVOY must not be administered as an intravenous push or bolus injection. When administered in combination with nivolumab or in combination with nivolumab and chemotherapy, nivolumab should be given first followed by YERVOY and then by chemotherapy (if applicable) on the same day. Use separate infusion bags and filters for each infusion. For instructions on the preparation and handling of the medicinal product before administration, see section 6.6.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 414, 3 November 2025

Products approved for additional indication (DCA 414 – 3 November 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
7.	AVAXIM 80U PEDIATRIC SUSPENSION FOR INJECTION [Inactivated Hepatitis A virus-GBM strain 80U]	**INDICATION (*POSOLOGY*) :** **Paediatric population** <u>Primary-vaccination</u> Primary vaccination is achieved with one vaccine dose of 0.5 mL. <u>Booster</u> **A 0.5 mL** booster dose of is recommended to **ensure** long term protection. This booster dose **should** be administered **6 months to 10 years** after the primary vaccination (see section 5.1). **In a context of high to intermediate endemicity, a single-dose or two-dose regimen (primary vaccination and booster) may be used in childhood vaccination programmes which is in agreement with the official recommendations.** <u>Method of administration</u> This vaccine must be administered by the intramuscular route. The recommended injection site is the deltoid region. In exceptional cases, the vaccine may be administered by the subcutaneous route in patients suffering from thrombocytopaenia or in patients at risk of haemorrhage. The vaccine should not be administered into the buttocks because of the varying amount of fat tissue in this region, that may contribute to variability in effectiveness of the vaccine. Do not inject by the intravascular route: ensure that the needle does not penetrate a blood vessel. Do not inject by the intradermal route.	**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.