Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 421, 8 Jun 2026

Products approved for additional indication (DCA 421 – 8 June 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Pluvicto 1000 MBq/mL Solution for Injection/Infusion [Lutetium (177Lu) vipivotide tetraxetan 1000 MBq/mL]	**INDICATION:** PLUVICTO is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy, and • are considered appropriate to delay taxane-based chemotherapy, or • have received prior taxane-based chemotherapy. **POSOLOGY:** <u>Important safety instructions</u> Pluvicto should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings and after evaluation of the patient by a qualified physician. Radiopharmaceuticals, including Pluvicto, should be used by or under the control of healthcare professionals who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorised to license the use of radiopharmaceuticals. <u>Patient identification</u> Patients should be identified for treatment by PSMA imaging.	**Novartis Corporation (Malaysia) Sdn. Bhd.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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		<u>Posology</u> The recommended treatment regimen of Pluvicto is 7 400 MBq intravenously every 6 weeks (±1 week) for a total of 6 doses, unless there is disease progression or unacceptable toxicity. Medical castration with a gonadotropin-releasing hormone (GnRH) analogue should be continued during treatment in patients not surgically castrated. *<u>Treatment monitoring</u>* Laboratory tests should be performed before and during treatment with Pluvicto. Dosing may need to be modified based on the test results (see Table 1). • Haematology (haemoglobin, white blood cell count, absolute neutrophil count, platelet count) • Kidney function (serum creatinine, calculated creatinine clearance [CLcr]) • Liver function (alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, blood serum albumin, total blood bilirubin) *<u>Dose modifications for adverse reactions</u>* Recommended dose modifications of Pluvicto for adverse reactions are provided in Table 1. Management of severe or intolerable adverse reactions may require temporary dose interruption, dose reduction or permanent discontinuation of treatment with Pluvicto. If a treatment delay due to an adverse reaction persists for >4 weeks, treatment discontinuation with Pluvicto may be considered. The dose of Pluvicto may be reduced by 20% to 5 900 MBq	

<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>once; the dose should not be re-escalated. If a patient has further adverse reactions that would require an additional dose reduction, treatment with Pluvicto must be discontinued.

Table 1 Recommended dose modifications of Pluvicto for adverse reactions
<table>
<tr><th>Adverse reaction</th><th>Severity[a]</th><th>Dose modification</th></tr>
<tr><td>Dry mouth</td><td>Grade 3</td><td>Reduce Pluvicto dose by 20% to 5 900 MBq.</td></tr>
<tr><td>Gastrointestinal toxicity</td><td>Grade ≥3 (not amenable to medical intervention)</td><td>Withhold Pluvicto until improvement to grade 2 or baseline.
Reduce Pluvicto dose by 20% to 5 900 MBq.</td></tr>
<tr><td>Myelosuppresion (anaemia, thrombocytopenia, leukopenia, neutropenia, pancytopenia)</td><td>Grade 2</td><td>Withhold Pluvicto until improvement to grade 1 or baseline.
Manage as deemed appropriate. The use of growth factors is permitted but should be discontinued once improved to grade 1 or baseline. Checking haematinic levels (iron, B12 and folate) and providing supplementation is advocated. Transfusions may be given as clinically indicated.</td></tr>
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				Grade ≥3	Withhold Pluvicto until improvement to grade 1 or baseline. Reduce Pluvicto dose by 20% to 5 900 MBq.	
			Renal toxicity	Defined as: • Confirmed serum creatinine increase (grade ≥2) • Confirmed CLcr <30 mL/min; calculate using Cockcroft Gault with actual body weight	Withhold Pluvicto until improvement.	
				Defined as: • Confirmed ≥40% increase from baseline serum creatinine And • Confirmed >40% decrease from baseline CLcr; calculate using Cockcroft-Gault with actual body weight	Withhold Pluvicto until improvement or return to baseline. Reduce Pluvicto dose by 20% to 5 900 MBq.	
				Recurrent renal toxicity (grade ≥3)	Permanently discontinue Pluvicto.	
			Spinal cord compression	Any	Withhold Pluvicto until the compression has been adequately treated and any	

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				neurological sequela have stabilised and ECOG performance status has stabilised.	
		Fracture in weight-bearing bones	Any	Withhold Pluvicto until the fracture has been adequately stabilised/treated and ECOG performance status has stabilised.	
		Fatigue	Grade ≥3	Withhold Pluvicto until improvement to Grade 2 or baseline.	
		Electrolyte or metabolic abnormalities	Grade ≥2	Withhold Pluvicto until improvement to Grade 1 or baseline.	
		Non-haematological toxicity (clinically significant, not otherwise stated)	Grade ≥2	Withhold Pluvicto until improvement to Grade 1 or baseline.	
		AST or ALT elevation	AST or ALT >20 times ULN in the absence of liver metastases	Permanently discontinue Pluvicto.	
		Abbreviations: CLcr, creatinine clearance; ECOG, Eastern Cooperative Oncology Group; AST, aspartate aminotransferase; ALT, alanine aminotransferase; ULN, upper limit of normal. Grading according to most current Common Terminology Criteria for Adverse Events (CTCAE).			

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		[a] The same thresholds are also applicable to baseline values at the time of treatment initiation with Pluvicto. *Special populations* *Elderly* No dose adjustment is recommended in patients aged 65 years or older. *Renal impairment* No dose adjustment is recommended for patients with mild to moderate renal impairment with baseline CLcr ≥30 mL/min by Cockcroft-Gault. Treatment with Pluvicto is not recommended in patients with moderate to severe renal impairment with baseline CLcr <30 mL/min or end-stage renal disease as the pharmacokinetic profile and safety of Pluvicto have not been studied in these patients (see sections 4.4 and 5.2). *Hepatic impairment* No dose adjustment is recommended for patients with hepatic impairment. Pluvicto has not been studied in patients with moderate or severe hepatic impairment (see section 5.2). *Paediatric population* There is no relevant use of Pluvicto in the paediatric population in the indication of treatment of PSMA-expressing prostate cancer.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	TEZSPIRE 210MG SOLUTION FOR INJECTION PRE-FILLED SYRINGE TEZSPIRE 210MG SOLUTION FOR INJECTION PRE-FILLED PEN [Tezepelumab 210 mg/ 1.91ml]	**INDICATION:** <u>Chronic rhinosinusitis with nasal polyps (CRSwNP)</u> TEZSPIRE is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control. **POSOLOGY:** 4.2 Posology and method of administration Treatment should be initiated by physicians experienced in the diagnosis and treatment of conditions for which TEZSPIRE is indicated (see section 4.1). Posology TEZSPIRE is intended for long-term treatment. A decision to continue the therapy should be made at least annually based on the patient's level of **disease** control. Asthma Adults and adolescents (aged 12 years and older) The recommended dose is 210 mg of tezepelumab by subcutaneous injection every 4 weeks. **CRSwNP** **The recommended dose for adult patients is 210 mg of tezepelumab by subcutaneous injection every 4 weeks.**	**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)
		Missed dose If a dose is missed, the dose should be administered as soon as possible. Thereafter, the patient can resume dosing on the scheduled day of administration. If the next dose is already due, then administer as planned. A double dose must not be administered. Special populations Elderly (65 years of age) No dose adjustment is required for elderly patients (see section 5.2). Renal and hepatic impairment No dose adjustment is required for patients with renal or hepatic impairment (see section 5.2). Paediatric population The safety and efficacy of TEZSPIRE in children under 12 years of age **for the treatment of asthma** have not been established. No data are available. **The safety and efficacy of TEZSPIRE in children under 18 years of age for the treatment of CRSwNP have not been established. No data are available.**	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Method of administration TEZSPIRE is administered as a subcutaneous injection. A patient may self-inject or the patient's caregiver may administer this medicinal product after training in subcutaneous injection technique. Proper training should be provided to patients and/or caregivers on the preparation and administration of TEZSPIRE prior to use according to the Instructions for Use. TEZSPIRE should be injected into the thigh or abdomen, except for the 5 cm around the navel. If a healthcare professional or caregiver administers the injection, the upper arm can also be used. A patient should not self-inject in the arm. It should not be injected into areas where the skin is tender, bruised, erythematous, or hardened. It is recommended to rotate the injection site with each injection. Comprehensive instructions for administration using the pre-filled syringe or pre-filled pen is provided in the Instructions for Use.	