Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 423, 6 Ogos 2026

Products approved for additional indication (DCA 423 – 6 August 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Abrysvo Powder and Solvent for Solution for Injection [-RSV subgroup A stabilized prefusion F protein 0.06mg/dose -RSV subgroup B stabilized prefusion F protein 0.06mg/dose]	**INDICATION:** The changes to the indication are in bold as below: Abrysvo is indicated for: • Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy. • Active immunisation of individuals **18 years of age and older** for the prevention of lower respiratory tract disease caused by RSV. The use of this vaccine should be in accordance with official recommendations. **POSOLOGY:** <u>Pregnant individuals</u> A single dose of 0.5 mL should be administered between weeks 24 and 36 of gestation. <u>Individuals **18 years of age and older**</u> A single dose of 0.5 mL should be administered. <u>Paediatric population</u> The safety and efficacy of Abrysvo in children (from birth to less than 18 years of age) have not yet been established. Limited data are available in pregnant adolescents and their infants.	**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.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 423, 6 Ogos 2026

Products approved for additional indication (DCA 423 – 6 August 2026)

<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>Method of administration</u>
Abrysvo is for intramuscular injection into the deltoid region of the upper arm.
The vaccine should not be mixed with any other vaccines or medicinal products.
For instructions on reconstitution and handling of the medicinal product before administration, see section 6.6 Special precautions for disposal and other handling.</td><td></td></tr>
<tr><td>2.</td><td>GAZYVA 1000 MG/ 40 ML CONCENTRATE FOR SOLUTION FOR INFUSION
[Obinutuzumab 25 mg/mL]</td><td>INDICATION:
<u>Lupus nephritis (LN)</u>
GAZYVA in combination with mycophenolate mofetil (MMF) is indicated for the treatment of adult patients with active Class III or IV, with or without concomitant Class V, lupus nephritis (LN).

POSOLOGY:
Lupus nephritis
The recommended dosage of GAZYVA is 1000 mg administered intravenously (see Table 5).

GAZYVA should be used in combination with mycophenolate mofetil.

Table 5: Dose of GAZYVA for patients with Lupus Nephritis
<table>
<tr><th>Dose number</th><th>Timing of treatment</th><th>Dose</th></tr>
<tr><td>1</td><td>Initial infusion</td><td>1000 mg</td></tr>
<tr><td>2</td><td>Week 2</td><td>1000 mg</td></tr>
</table></td><td>ROCHE (MALAYSIA) SDN. BHD.
Level 21, The Pinnacle,
Persiaran Lagoon,
Bandar Sunway,
47500 Subang 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></td><td>(two weeks after Dose 1)</td><td></td></tr>
<tr><td>3</td><td>Week 24</td><td>1000 mg</td></tr>
<tr><td>4</td><td>Week 26
(two weeks after Dose 3)</td><td>1000 mg</td></tr>
<tr><td>5*
and thereafter</td><td>Every 6 months</td><td>1000 mg</td></tr>
</table>
*Dose 5 should be administered six months after Dose 4
The patient's condition and response should be evaluated at Week 76 and beyond, and an appropriate risk-benefit analysis should be made for continuation of therapy.
The initial GAZYVA infusion should be administered at the standard infusion rate (see Table 6)
Table 6: Lupus nephritis: Standard infusion rate
<table>
<tr><th>Dose number</th><th>Timing of treatment</th><th>Rate of infusion</th></tr>
<tr><td>1</td><td>Initial infusion
(1000 mg)</td><td>Administer at a rate of 50 mg/hr. the rate of infusion can be escalated in 50 mg/hr increments every 30 minutes to a maximum of 400 mg/hr. for management of IRRs that occur</td></tr>
</table>
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 423, 6 Ogos 2026

Products approved for additional indication (DCA 423 – 6 August 2026)

<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></td><td></td><td>during infusion, refer to section Dosage modifications during treatment (all indications).</td></tr>
<tr><td>2</td><td>Week 2 – two weeks after Dose 1
(1000 mg)</td><td rowspan="4">Administer at a rate of 100 mg/hr. the rate of infusion can be escalated at a rate of 100 mg/hr every 30 minutes to a maximum of 400 mg/hr.</td></tr>
<tr><td>3</td><td>Week 24
(1000 mg)</td></tr>
<tr><td>4</td><td>Week 26 – two weeks after Dose 3
(1000 mg)</td></tr>
<tr><td>5*
and thereafter</td><td>Every 6 months
(1000 mg)</td></tr>
</table>
*Dose 5 should be administered six months after Dose 4

Delayed or missed doses (LN)
If a planned dose of GAZYVA is missed, it should be administered as soon as possible - do not wait until the next planned dose. The schedule of administration should be adjusted to maintain the appropriate interval between doses.
</td><td></td></tr>
</table>