Immedica submits pegzilarginase application to the Australian Therapeutic Goods Administration (TGA)

Stockholm, Sweden, December 9, 2025 – Immedica today announced that it has submitted a prescription medicine application for pegzilarginase to the Australian Therapeutic Goods Administration (TGA). The TGA has issued a Milestone 2 Notification Letter confirming that the application has successfully passed preliminary assessment under the Therapeutic Goods Act 1989.

The application is now considered effective and has been formally accepted for evaluation, representing the next step toward potential inclusion of pegzilarginase in the Australian Register of Therapeutic Goods (ARTG).

“We are pleased to have achieved this milestone with the TGA,” said Anders Edvell, CEO. “The acceptance of our application for evaluation is an important step in making pegzilarginase available to patients in Australia living with this severe and ultra-rare condition.”

About pegzilarginase
Pegzilarginase is a novel recombinant human enzyme and has been shown to rapidly and sustainably lower levels of the amino acid arginine and its toxic metabolites in plasma accompanied by improvements in clinical outcomes.

About ARG1-D
ARG1-D is one of the eight urea cycle disorder (UCD) subtypes. It shares overlapping features with other UCDs and the most prominent is the impairment in excreting nitrogen. However, in ARG1-D, hyperammonemia is generally less severe and instead these patients show spasticity, which other subtypes do not. The principal defect in ARG1-D leads to accumulation of plasma arginine and its toxic metabolites, which occurs in almost all patients with this disorder. Patients are often diagnosed in late infancy or early childhood and the symptoms include spasticity, seizures, developmental delay, intellectual disability, and early mortality.

About Immedica
Immedica is a pharmaceutical company, headquartered in Stockholm, Sweden, focused on the commercialization of medicines for rare diseases and specialty care products. Immedica’s capabilities cover marketing and sales, compliance, pharmacovigilance, quality assurance, regulatory, medical affairs and market access, as well as a global distribution network serving patients in more than 50 countries. Immedica is fully dedicated to helping those living with diseases which have a large unmet medical need. Immedica’s therapeutic areas are within RARE metabolic, RARE hematology & oncology, RARE neurology and specialty care. Immedica was founded in 2018 and employs today around 160 people across Europe, the Middle East and the United States. Immedica is backed by the investment firms KKR and Impilo.

For more information visit www.immedica.com.

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