Immedica announces FDA acceptance of pegzilarginase BLA resubmission in the U.S.

Stockholm, Sweden, January 14, 2026, - Immedica Pharma AB today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmission of the Biologics License Application (BLA) for pegzilarginase for the treatment of arginase 1 deficiency, an ultra-rare and serious inherited metabolic disorder.

The FDA has classified the application as a Class 1 resubmission, and has assigned a PDUFA target action date of February 23, 2026.

“We appreciate the FDA’s acceptance of our BLA resubmission and the constructive dialogue throughout the review process,” said Anders Edvell, CEO of Immedica. “The assignment of a PDUFA target action date represents an important step forward for pegzilarginase. We remain focused on advancing this application with the goal of making a potential new treatment available to patients living with arginase 1 deficiency, a rare and serious condition with significant unmet medical need.”

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. Loargys is approved in the EU, UK and Oman for the treatment of arginase 1 deficiency (ARG1-D), also known as hyperargininemia, in adults, adolescents and children aged 2 years and older. It is the first and only disease-modifying treatment for ARG1-D.

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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