Loargys® (pegzilarginase) approved in Great Britain for treatment of arginase 1 deficiency (ARG1-D)

Stockholm, 21, 2023: Immedica today announces that the Medicines & Healthcare products Regulatory Agency in the UK has granted marketing authorization of Loargys® (pegzilarginase) for the treatment of arginase 1 deficiency (ARG1-D), also known as hyperargininaemia, in adults, adolescents and children aged 2 years and older. Orphan Designation in Great Britain was also granted.

Anders Edvell, CEO of Immedica commented “This has indeed been an exciting week for Immedica with the approval in the EU on December 15 and now this approval in Great Britain, being one of the major markets in Europe.”

Mark Bell, General Manager UK and Ireland commented: “This is a very important approval for the people living with ARG1-D and their families across the whole of United Kingdom and proof of the huge unmet medical need in this ultra rare disease. We will now focus on getting Loargys available to patients in the UK as soon as possible”

The approval is based on data from the clinical development program of pegzilarginase for ARG1-D providing evidence of clinically relevant outcomes and balanced safety profile, including the phase 3 randomized, double-blind, placebo-controlled study named PEACE (CAEB1102-300A), supported by the phase 2 open-label long-term study (CAEB1102-102A).

About Loargys®
Loargys (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 and Great Britain for the treatment arginase 1 deficiency, also known as hyperargininaemia, in adults, adolescents and children aged 2 years and older and is the first and only disease modifying treatment in 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 genetic & metabolic diseases, hematology & oncology and specialty care.

Immedica was founded in 2018 by the investment company Impilo and Buy-in-Management. Today Immedica employs more than 100 people across Europe and the Middle East.

For more information visit www.immedica.com

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