Immedica receives marketing authorization approval for Loargys® (pegzilarginase) in Australia

STOCKHOLM, Sweden, November 23 - Immedica announces that the Australian Therapeutic Goods Administration (TGA) has approved Loargys® (pegzilarginase) for the treatment of arginase 1 deficiency (ARG1-D), also known as hyperargininemia, in adults, adolescents and children aged 2 years and older.

"The TGA approval of Loargys is an important milestone for Immedica and for patients and families living with ARG1-D in Australia," said Anders Edvell, CEO of Immedica. "This is our first marketing approval in the Oceania region, and we are proud to be able to offer a treatment option to a patient community that has waited a long time for one."

About ARG1-D
ARG1-D is an ultra-rare, progressive and serious inherited metabolic disorder. The principal defect in ARG1-D leads to accumulation of plasma arginine (hyperargininemia) and its toxic metabolites. Patients are often diagnosed in late infancy or early childhood, and the symptoms include spasticity, seizures, developmental delay, intellectual disability, and early mortality. ARG1-D is one of the eight urea cycle disorder (UCD) subtypes. It shares some overlapping features with other UCDs, including impaired nitrogen excretion. However, in ARG1-D, hyperammonemia is generally less severe.

About Loargys® (pegzilarginase)
Loargys is a novel, recombinant, human arginase-1 enzyme that has been shown to rapidly and sustainably lower levels of the amino acid arginine and its toxic metabolites in plasma, making it the first and only therapy proven to lower plasma arginine. Loargys is approved in the EU, UK, US, Oman, Canada, Saudi Arabia and Australia.

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, RARE endocrinology and specialty care. Immedica was founded in 2018 and employs today around 200 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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