



Immedica intends to re-submit the BLA seeking approval of Loargys® (pegzilarginase) for treatment of arginase 1 deficiency (ARG1-D) in the US

Stockholm, December 21, 2023: Immedica today announces its intention to re-submit the biologics license application (BLA) seeking approval of Loargys® (pegzilarginase) for the treatment of arginase 1 deficiency (ARG1-D) in the US during 2024.

The decision was taken following the recent approval of Loargys by the European Commission on December 15 and after a dialogue with the FDA.

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 for the treatment of arginase 1 deficiency, also known as hyperargininemia, in adults, adolescents and children aged 2 years and older, and is the first and only disease modifying treatment for ARG1-D. EMA CHMP summary of opinion is available [here](#).

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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