Immedica acquires global rights to pegzilarginase from Aeglea

Stockholm, July 27, 2023 – Immedica announces that it has signed an agreement to acquire the global rights to pegzilarginase and related assets from Aeglea BioTherapeutics, Inc. The acquisition means that the previously entered exclusive license and supply agreement from 2021 of the rights to pegzilarginase in Europe and the Middle East will be superseded.

Anders Edvell, Immedica CEO commented: “We are very pleased with this new agreement with Aeglea, giving us the global rights to pegzilarginase. People with arginase 1 deficiency lack sufficient treatment options today and we believe that pegzilarginase, where awarded marketing authorizations, has the potential to benefit these patients as the first disease modifying treatment.”

He continues. “Pegzilarginase is currently under review by the European Medicines Agency, and we will seek to initiate a dialogue with the US FDA to discuss a path forward for a potential regulatory assessment also in the US”.

Financial terms
Immedica will pay an upfront to Aeglea of USD 15 million. In addition, Aeglea may receive milestones of up to USD 100 million triggered inter alia by formal product reimbursement by national authorities in some key European markets and a potential US marketing authorization granted by the FDA.

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. Pegzilarginase has been developed for the treatment of people with the urea cycle disorder arginase 1 deficiency (ARG1-D).

Pegzilarginase is currently not approved in any market or indication. It is currently under review by the European Medicinal Agency, EMA.

About arginase 1 deficiency
Arginase 1 deficiency (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 Pharma
Immedica is 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 and 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 90 people across Europe and the Middle East.

For more information visit www.immedica.com

Immedica contact:
Linda Holmström
Head of Communication
linda.holmstrom@immedica.com
+ 46 708 73 40 95

Immedica Pharma AB
Solnavägen 3H
SE-113 63 Stockholm