Ravicti® (glycerol phenylbutyrate) approved by the Taiwan Food and Drug Administration (TFDA) for the treatment of Urea Cycle Disorders

Stockholm, March 21, 2024 – Immedica and its partner WinHealth Pharma announce that the Taiwan Food and Drug Administration (TFDA) has granted marketing authorization for Ravicti® (glycerol phenylbutyrate) for use as adjunctive therapy for chronic management of patients with urea cycle disorders (UCDs) including deficiencies of carbamoyl phosphate synthetase I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements). Ravicti is not indicated for the treatment of acute hyperammonemia in patients with UCDs.

Anders Edvell, CEO Immedica comments: “We are pleased to announce the approval of Ravicti in Taiwan, marking a significant milestone in our commitment to providing effective treatments for urea cycle disorders. This achievement underscores our dedication to expanding global access to life-changing therapies.”.

In December 2020, WinHealth Pharma and Immedica Pharma AB entered an agreement under which WinHealth Pharma gained the exclusive commercial rights to glycerol phenylbutyrate oral liquid, in a territory covering the Greater China Area, South Korea, Singapore, Vietnam, Indonesia, Malaysia, Philippines and Thailand.

About Urea Cycle Disorders (UCD)
Urea cycle disorders are a group of metabolic diseases that affect a specific enzyme or transporter in the urea cycle leading to elevated ammonia or glutamine levels in the circulation. Symptoms of the disorder can begin at any age, with more severe defects beginning early in life. UCD patients may experience episodes, called hyperammonemic crises, when ammonia levels in the blood become excessively high, which can result in irreversible brain damage, coma, or death. Beyond hyperammonemic crises there are also more subtle symptoms including vomiting, refusal to feed, irritability, muscular hypotonia as well as delayed motor and psychointellectual development. As a group, these disorders occur in 1 in 35,000 newborns. Read more about urea cycle disordes here: www.ucdandyou.com

About Ravicti® (glycerol phenylbutyrate)
Ravicti is a medicine used to treat patients of all ages with UCDs, including deficiencies of carbamoyl phosphate synthetase I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie

supplements).

The medicine is used to reduce the amount of ammonia in the blood in order to reduce the risk of neurological consequences.

About Winhealth Pharma
Hong Kong Winhealth Pharma Group ("Winhealth Pharma") is a China-based, global innovative biomedical company founded in 2006, providing novel breakthrough therapies to patients with rare diseases and other unmet medical needs. The Group has established long-term strategic partnership with dozens of world-leading biotechnology companies. It has built a unique, balanced and diversified portfolio with numerous orphan drugs and specialty products at commercial and late clinical stages and will continuously look to bring in more innovative therapies from the globe. Read more at www.winhealthpharma.com

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

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