



Glycerol phenylbutyrate approved by the National Medical Products Administration in China for the treatment of Urea Cycle Disorders

Stockholm, June 21, 2023 – Immedica's partner Hongkong WinHealth Pharma Group Co.Ltd has announced that glycerol phenylbutyrate oral liquid has gained approval for chronic management of patients with urea cycle disorders (UCDs) including deficiencies of carbamoyl phosphate synthetase I (CPS), ornithine carbamoyltransferase (OTC), Citrullinemia type 1, argininosuccinuria, argininemia and hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

Glycerol phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Anders Edvell, CEO Immedica commented: "People living with UCDs in China face problems such as insufficient diagnosis and treatment levels as well as lack of treatment options. The approval of glycerol phenylbutyrate in China is therefore of great significance and has the potential to improve the life for these patients and their families."

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.

About glycerol phenylbutyrate

Glycerol phenylbutyrate 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. 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 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 as well as market access. 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

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