



Ravicti® (glycerol phenylbutyrate) approved by the National Administration of Drugs, Food and Medical Devices in Argentina for treatment of urea cycle disorders

Stockholm, September 29, 2023 – Immedica and its partner Innovative Medicines AS announces that the National Administration of Drugs, Food and Medical Devices (ANMAT) in Argentina has granted marketing authorization for Ravicti® (glycerol phenylbutyrate) 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.

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)

Anders Edvell, CEO Immedica commented: "This approval by ANMAT is an important milestone for the people living with UCDs in Argentina and addresses the significant unmet medical need in this patient population".

In 2021 Innovative Medicines and Immedica Pharma signed an agreement for the exclusive distribution and marketing of Ravicti and Ammonaps (sodium phenylbutyrate) for Argentina, Brazil Colombia, and other territories in Latin America.

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 Ravicti®

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

About Innovative Medicines AS

Innovative Medicines AS also called iMed Group is a privately held company created with the objective of filling the very specific and special medical needs of a small population of adults and children seeking life-preserving therapeutics for rare diseases.

Following the leadership of our partners around the world and under the management of a highly experienced team, iMed Group pursues the objective of becoming the leading biopharmaceutical research company in Latin America. To learn more about Innovative Medicines, please visit <http://imedicinesgroup.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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