# NMPA Grants Priority Review to NDA for Glycerol Phenylbutyrate

Immedica Pharma AB is pleased to announce that RAVICTI® (glycerol phenylbutyrate), has been accepted and granted Priority Review for the New Drug Application (NDA) in China. This has been presented earlier by our partner WinHealth (see full press release below).

In April, another submission for RAVICTI® Market Authorisation Approval was accepted by the Department of Health (DoH) in HongKong.

*"With these submissions in China and HongKong, Immedica continues to rapidly bring Ravicti to patients globally. We remain confident in Ravicti's potential to change the current management of Urea Cycle Disorders in this part of the world",* says Anders Edvell, CEO of Immedica.

The pressrelease from WinHealth, follows below.

## NMPA Grants Priority Review to NDA for Glycerol Phenylbutyrate

[Beijing, China, August 22, 2022] Mr. Jack Wang, founder, chairman and CEO of Hong Kong Winhealth Pharma Group ("Winhealth Pharma") announced today that the National Medical Products Administration (NMPA) has accepted and granted Priority Review for the New Drug Application (NDA) of "glycerol phenylbutyrate" (a new drug product for rare disease) which is pre-marketing clinical study waiver in China. This is of great significance for rapid access to new drugs in patients with urea cycle disorders (UCDs) in China. As an innovative biopharmaceutical company, Winhealth Pharma has always adhered to its original intention of "Patient Comes First". The acceptance of NDA regarding glycerol phenylbutyrate reflects our commitment and practice in providing innovative therapies for patients with rare diseases and other unmet medical needs.

The proposed indication for glycerol phenylbutyrate in China is the chronic management of patients with UCDs that cannot be managed with protein restriction and/or amino acid supplementation alone. Urea cycle disorders (UCDs) are rare inherited metabolic disorders characterized by hyperammonemia that arise in either the neonatal period or later. The clinical manifestations include changes in the level of consciousness similar to encephalitis or drug intoxication, acute encephalopathy, epilepsy, lethargy, and mental disorders. Hyperammonemia may lead to severe neurocognitive impairment, coma, and even death.

In December 2020, Winhealth Pharma signed an agreement with Immedica Pharma AB, under which Winhealth Pharma was granted exclusive commercialization rights for glycerol phenylbutyrate in Greater China, South Korea, Singapore, Vietnam, Indonesia, Malaysia, the Philippines and Thailand.

**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 AB**

Immedica is a fast-growing private niche pharma group with headquarter in Stockholm, Sweden and commercial coverage across Europe and the Middle East. Immedica has significant know-how and experience in commercialization of niche/specialty care products across Europe and the Middle East, and the company's management team has an outstanding track record of operating niche pharma products internationally. Immedica has capabilities to provide optimal access of specialty care medicines to patients with significant medical needs, including key areas such as regulatory affairs, pharmacovigilance, medical affairs, pricing & reimbursement, quality, and product distribution. More information is available at www.immedica.com

**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. As a group, these disorders occur in 1 in 30,000 newborns in the territories where Immedica has the product rights.

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