
SAPROPTERIN DIHYDROCHLORIDE SACHETS AND TABLETS ARE NOW AVAILABLE IN THE UNITED KINGDOM

FOR IMMEDIATE RELEASE

Chiasso, Switzerland and Reading, England, October 4th, 2023 – Dipharma SA (“Dipharma”) and LogixX Pharma (“LogixX”) are delighted to announce the official launch of Sapropterin Dihydrochloride (“Sapropterin”) in the United Kingdom.

Sapropterin Dihydrochloride, a generic equivalent to Kuvan[®], is now available in all dosage forms, including sugar free soluble tablets of 100mg strength. What makes this launch even more noteworthy is the introduction of Sapropterin Dihydrochloride in powder form for oral solution, available in 100mg and 500mg strengths, marking the first-ever release of this formulation in the UK.

Marc-Olivier Geinoz, CEO of Dipharma, expressed his enthusiasm, stating, “After successfully introducing Sapropterin Dipharma in several major European countries, we are excited to announce its launch also in the UK. This achievement is the result of a strong collaboration with our esteemed UK partner, LogixX. Starting today, patients in the UK will have access to Sapropterin Dihydrochloride in the convenient powder for oral solution form. This innovative formulation, which dissolves 25 times faster than tablets, represents a significant advancement in patient compliance and their overall quality of life. Dipharma and LogixX remain steadfast in their commitment to supporting the PKU and BH4 deficiency community, with a continued presence in the UK territory and active engagement with healthcare professionals.”

He further highlighted, “All our Sapropterin Dihydrochloride products boast an impressive 36-month shelf life, underscoring our dedication to environmental sustainability by reducing the risk of product wastage, while also affirming the quality and stability of our drug.”

This achievement marks a significant milestone in Dipharma's history, solidifying its presence with Sapropterin Dipharma in all the major European countries.

Michael Close, CEO of LogixX Pharma, added, “We are proud to be part of this milestone, bringing innovative solutions to patients in the UK. This partnership signifies our dedication to improving the lives of individuals with PKU and BH4 deficiency with Swiss made products in a range of formulation and dosage types for these important patient groups. We look forward to a continued fruitful collaboration with Dipharma.”

About BH4-responsive phenylketonuria and BH4 deficiency

PKU is a rare, genetic metabolic disorder that affects an estimated 1 in 7000+ newborn infants. In those affected, there is a reduction in the activity of the enzyme phenylalanine hydroxylase (PAH). This defect impairs the degradation of the amino acid phenylalanine (Phe) into tyrosine (Tyr) and promotes

hyperphenylalaninemia. Left untreated, hyperphenylalaninemia can lead to progressive and irreversible central nervous system damage. This deficiency manifests as mental and physical impairments, such as loss of emotionality and inappropriate changes in behavior. Nowadays, PKU can be diagnosed and treated early through newborn screening. In addition, PKU is linked to another rare condition, tetrahydrobiopterin (BH4) deficiency disorder (incidence of 1 to 2 in 1,000,000). Here, the synthesis or regeneration of BH4, the essential cofactor of PAH, is impaired. This results in hyperphenylalaninemia and a deficiency of the monoamine neurotransmitters, dopamine, serotonin, noradrenaline and epinephrine. The effects on those affected by these conditions depend on a particular genetic mutation that underlies the disease. For more information on these diseases, please visit www.dipharma.ch/metabolic-diseases/.

About Sapropterin

Sapropterin dihydrochloride is a synthetic version of the naturally occurring 6R-BH4, which is a cofactor of the hydroxylases for phenylalanine, tyrosine and tryptophan. Sapropterin formulations are administered to patients with BH4-responsive phenylketonuria and BH4 deficiency. In patients with phenylketonuria, sapropterin enhances the activity of the defective phenylalanine hydroxylase and thereby increases or restores the oxidative metabolism of phenylalanine (“Phe”) sufficiently to reduce or maintain blood Phe levels, prevent or minimize further Phe accumulation, and increase tolerance to Phe intake in the diet. In patients with BH4 deficiency, sapropterin formulations complements the deficient levels of BH4, thereby restoring the activity of phenylalanine hydroxylase.

About Dipharma

Dipharma SA is a Swiss specialty pharmaceutical company, developing high quality, improved, medicines for rare diseases. Dipharma SA is part of a third-generation group of family-owned companies that have grown to a global presence.

With a portfolio of generic orphan products for the treatment of Hyperphenylalaninemia, Gaucher Disease, Hereditary Tyrosinemia Type 1, Urea Cycle Disorders and others, Dipharma SA provides improved solutions for patients affected by inborn metabolic diseases at an affordable cost and with a global reach. For more information, please visit www.dipharma.ch

About LogixX Pharma

LogixX Pharma is a specialty pharmaceutical company based in Berkshire, United Kingdom. LogixX Pharma was founded in 2010 and is an independent, privately owned entrepreneurial and dynamic enterprise - with core competencies in the fields of pharmaceuticals and medical devices.

The management and treatment of niche therapeutic conditions represents an exciting growth opportunity for LogixX. Many of these conditions are poorly treated with a high level of unmet medical need, so we are proud to be a part of the solution for these patients.

LogixX Pharma’s mission is to bring new therapies to patients, new treatment approaches to healthcare professionals and better health outcomes for all.

For more information, please visit www.logixxpharma.co.uk

Kuvan® is a registered trademark of Biomarin. In the European Union Kuvan® was approved in December 2008 for the treatment of hyperphenylalaninemia (HPA) in adults and pediatric patients of all ages with phenylketonuria (PKU) or tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment.

DISCLAIMER

This press release may contain certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those anticipated in the forward-looking statements. The company assumes no responsibility to update forward-looking statements or adapt them to future events or developments.

Dipharma SA and LogixX Pharma operates respectfully of any third-party IP rights and/or regulatory exclusivities that may exists in each specific country.

This press release may contain information on pharmaceuticals that are not currently approved or available in your country or region.

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