Dipharma

Better Together.

Improved Solutions for Rare Diseases.

SAPROPTERIN DIPHARMA IS NOW AVAILABLE IN EUROPE AND SWITZERLAND

Chiasso, Switzerland, July 3rd, 2023 – – Dipharma SA ("Dipharma") today announced that its product Sapropterin Dipharma is now available in main European Countries and in Switzerland.

Sapropterin Dipharma is available in the form of soluble tablets 100mg, powder for oral solution 100mg and powder for oral solution 500mg. The product is made in Switzerland with key supplies all manufactured in Europe, complying with the most stringent European environmental and safety standards.

Sapropterin Dipharma is a generic equivalent to Kuvan® and indicated for the treatment of BH4 deficiency and BH4-responsive phenylketonuria (PKU) patients.

Sapropterin Dipharma is distributed in Switzerland directly by Dipharma SA, in Germany by our subsidiary Dipharma Arzneimittel GmbH and in the other European countries by a network of reputable selected partners.

"I am proud to announce the launch of our product Sapropterin Dipharma in the main EU markets as well as in Switzerland. This launch represents for Dipharma the accomplishment of a 40-year long story, started when our partner Dr. Schircks first synthetized sapropterin dihydrochloride and administered it to hyperphenylalaninemia patients. Sapropterin Dipharma is the result of this partnership, bringing into the European market the first generic sapropterin product available with the full range of strengths and formulations." - said Mr. Marc-Olivier Geinoz, CEO of Dipharma – *"The patients will also benefit from having access to our sapropterin powder sachets, which dissolve in water much faster than the tablets. Indeed, Sapropterin should be placed in a glass or cup of water and stirred until dissolved, an operation which typically takes several minutes. With Sapropterin powder formulation, this operation is performed in a matter of seconds, which is expected to have a positive impact on treatment compliance and quality of life. Allow me to express my gratitude to the entire Dipharma team who has been working hard and with great passion for several years to achieve this result."*

This achievement, along with the recent approval by MHRA for the United Kingdom, witnesses the commitment of Dipharma to provide improved generic medicines to patients affected by rare 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 approved for the treatment of 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 complement 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

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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.

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