DIPHARMA AND LOGIXX PHARMA ANNOUNCE GRANTING OF MARKETING AUTHORISATION APPROVAL FOR GENERIC SAPROPTERIN IN UNITED KINGDOM

Chiasso, Switzerland and Reading, England, June 27, 2023 – Dipharma SA ("Dipharma") and LogixX Pharma ("LogixX") are pleased to announce that the Medicines and Healthcare Products Regulatory Agency ("MHRA") has granted Marketing Authorization for their generic product Sapropterin Dihydrochloride ("Sapropterin").

Sapropterin Dihydrochloride is a generic equivalent to Kuvan® and is available in the form of soluble tablets 100mg and – for the first time in the UK – powder for oral solution 100mg and powder for oral solution 500mg.

"*After the approval we received by Swissmedic and the European Medicine Authority, we are pleased to announce that also the MHRA has now approved our Sapropterin in all the available dosages and formulations for the UK market*" - said Marc-Olivier Geinoz, CEO of Dipharma – "*We achieved this result thanks to the collaboration between Dipharma and our UK partner LogixX. British patients will benefit by having access, for the first-time, to a sapropterin dihydrochloride product now also available in powder formulation. 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. This approval, along with the imminent launch of our sapropterin products in the European Union, reinforces our aim of bringing additional value to patients, coupling this with sustainability principles for National Healthcare System*."

Dipharma and LogixX are planning to launch the product into the UK market in the third quarter of 2023, shortly after the launch in Europe.

LogixX Pharma's C.E.O. Michael Close said "*there is great synergy between both companies. This opportunity combines Dipharma's expertise in developing and manufacturing rare and metabolic disease treatments and LogixX Pharma's expertise in launching novel and rare disease pharmaceuticals to the UK market. This partnership strengthens LogixX's own mission to bring new therapies to patients, new treatment approaches for healthcare professionals and better health outcomes for all*".

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

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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.

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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