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## DIPHARMA ANNOUNCES SUCCESSFUL DEVELOPMENT OF A STABLE, FAST DISSOLVING TABLET FORMULATION OF CARGLUMIC ACID

Dipharma strengthens its pipeline of improved formulations for the treatment of patients suffering from inborn errors of metabolism.

**Chiasso, Switzerland, April 4<sup>th</sup>, 2017** – Dipharma S.A. announces the successful development of a new, fast dissolving formulation of Carglumic acid tablets stable at room temperature.

Carglumic acid is a key therapeutic tool in the management of rare, life threatening inborn metabolic disorders affecting the urea cycle; as such it was a natural candidate for the Company's products portfolio.

"This achievement is another milestone in the expansion of our pipeline, aimed at improving the life of patients suffering from inborn errors of metabolism." commented Marc-Olivier Geinoz, CEO of Dipharma S.A. "We worked hard to develop an improved formulation meeting patients' requirements: today our R&D efforts were rewarded with the confirmation that our new formulation is fast dissolving and stable at room temperature".

Dipharma S.A. also announces the filing of a patent application claiming new fast dissolving and stable tablet formulations of Carglumic acid, together with the proprietary technology developed to improve the product stability, without modifying the pharmaceutical form the patients are familiar to.

Carglumic acid formulation is the fourth Dipharma product approaching the market: Diterin® (sapropterin dihydrochloride 100 mg tabs) has already been approved in South Korea and Russia for the treatment of hyperphenylalaninemia (HPA) due to phenylketonuria (PKU), Miglustat (miglustat 100 mg caps) was submitted in the USA through an abbreviated new drug application (ANDA) in 2016 for the treatment of Gaucher disease and Disanit® (nitisinone capsules) was submitted in EU in the last quarter of 2016 for the treatment of hereditary tyrosinemia type I. Dipharma also confirms that the development of several other products for the treatment of rare metabolic diseases is on- going.

## **About Carglumic acid**

Carglumic acid tablets 200mg (Carbaglu®) is a prescription drug used in the management of high ammonia levels due to rare inborn errors of metabolism affecting the urea cycle.

For more information on urea cycle disorders, please visit <a href="http://www.dipharma.ch/rare-diseases/">http://www.dipharma.ch/rare-diseases/</a>.

## **About Dipharma**

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

With a portfolio of products for the treatment of Phenylketonuria, Gaucher Disease, Niemann Pick Type C, Hereditary Tyrosinemia Type 1, Urea Cycle Disorders and others, Dipharma SA works every day to provide improved solutions for people affected by inborn metabolic diseases at an affordable cost and with a global reach.

For more information, please visit www.dipharma.ch

Carbaglu® is a registered trademark of Orphan Europe

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