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CONTACTS AMERIGEN: +1 (732) 993-9821
info@amerigenpharma.com
www.amerigenpharma.com

DIPHARMA: +41(0)916011700
info@dipharma.ch
www.dipharma.ch

AMERIGEN AND DIPHARMA ANNOUNCE U.S. FDA APPROVAL FOR GENERIC MIGLUSTAT 100 MG CAPSULES

The first generic version of Miglustat is now approved in the U.S.

Lyndhurst, N.J. and Chiasso, Switzerland. **April 18th, 2018** - Amerigen Pharmaceuticals Limited ("Amerigen") and Dipharma S.A. ("Dipharma") today announced that Amerigen's Abbreviated New Drug Application ("ANDA") for Miglustat 100 mg capsules has received final approval from the U.S. Food and Drug Administration. This is the first such ANDA to be approved as a generic equivalent to Actelion Pharmaceuticals' Zavesca®. The ANDA filing was the result of an exclusive collaboration between Amerigen and Dipharma in developing and commercializing Miglustat 100 mg capsules worldwide. Miglustat active ingredient is supplied to Amerigen by Dipharma who holds two granted U.S. patents, US9079856B2 and US8802155B1, one pertaining to a method of synthesis for miglustat and the other for a crystalline form of the same. Amerigen has the right to enforce these patents in the U.S. whilst Amerigen's affiliates will manufacture the finished product and commercialize it in the U.S., where it has already been launched.

Miglustat is a glucosylceramide synthase inhibitor indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option.

John Lowry, Amerigen's President and CEO, commented "*We are delighted to launch this product following a fruitful collaboration with Dipharma. This is Amerigen's fifth U.S. product launch and the third time we have brought a first generic to market, with important savings for the American healthcare system*."

Marc-Olivier Geinoz, Chief Executive Officer of Dipharma, expressed his satisfaction regarding the collaboration with Amerigen. "*This marks the first approval of a series of products our group has been developing in collaboration with Amerigen for various markets.*" he said. "*Thanks to this approval, chronically ill US patients and payers will have available a high quality, more affordable alternative to current treatment. For our young company it is a great achievement and it marks a significant milestone in our growth strategy*".

About Amerigen

Amerigen Pharmaceuticals is a group of companies engaged in all phases of the generic pharmaceutical business, with operations in the US and China. The group is controlled by Amerigen Pharmaceuticals Limited. The US regulatory and commercial activities within the group are conducted by Amerigen Pharmaceuticals Inc., based in Lyndhurst, NJ, USA. The group's Chinese subsidiary, Suzhou Amerigen Pharmaceutical Company Limited, is located in Suzhou, Jiangsu Province.

The group has products on the market currently in both the US and China plus an active portfolio of products under development, filed, or intended for filing, as ANDA's with the US FDA and the Chinese CFDA. Amerigen's focus is orally delivered products that are challenging to develop, require specialized technologies or high containment to manufacture, and present complex regulatory and intellectual property obstacles to bring to market. All Amerigen's products are developed and manufactured by the company or its partners around the world to meet the highest quality standards, including the US FDA.

About Dipharma

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

With a portfolio of generic orphan 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

Zavesca® is a registered trademark of Actelion Pharmaceuticals. The U.S. FDA approved Zavesca® in July 2003.