
DIPHARMA ANNOUNCES GRANT OF CENTRALISED MARKETING AUTHORIZATION FOR GENERIC MIGLUSTAT IN EUROPE

Chiasso, Switzerland, February 20th, 2019 – – Dipharma S.A. (“Dipharma”) today announced that the European Commission has granted Marketing Authorization of its generic Miglustat. This authorization comes after CHMP positive opinion last December in the frame of a centralized procedure at European Medicine Agency. Miglustat Dipharma 100 mg capsules has thus received authorization for all the 31 countries of the European Economic Area.

Miglustat Dipharma is a generic equivalent to Actelion’s (Johnson & Johnson) Zavesca®, and it can be stored at room temperature for 36 months. Dipharma owns IP rights on the Miglustat active substance, notably in U.S. and Europe.

“After our partner, Amerigen Pharmaceuticals Limited, successfully launched the first generic formulation of Miglustat in the United States of America 10 months ago, we are now proud to bring this product to the European patients” said Mr. Marc-Olivier Geinoz, CEO of Dipharma.

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 to a global presence.

With a portfolio of generic orphan products for the treatment of Phenylketonuria, Gaucher Disease, Hereditary Tyrosinemia Type 1, Urea Cycle Disorders and others, Dipharma S.A. 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

Zavesca® is a registered trademark of Actelion (Johnson & Johnson). In the European Union Zavesca® was first approved in November 2002 for the treatment of type 1 Gaucher Disease and in January 2009 it obtained authorization for the treatment of Niemann-Pick disease type C.

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 S.A. operates respectfully of any third party IP rights and/or regulatory exclusivities that may exist in each specific country.

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