FOR IMMEDIATE RELEASE

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Dipharma
Better Together.
Improved Solutions for Rare Diseases.

DIPHARMA ANNOUNCES FDA ACCEPTANCE OF ABBREVIATED NEW DRUG APPLICATION (ANDA) OF GENERIC NITISINONE FOR REVIEW

Chiasso, Switzerland, January 24th, 2019 – Dipharma S.A. ("Dipharma") today announced that the U.S. Food and Drug Administration (FDA) accepted its nitisinone abbreviated new drug application (ANDA) for review. Nitisinone is a generic equivalent to Swedish Orphan/SOBI's Orfadin®. Nitisinone active substance master file is also owned by the Dipharma Group, which has been supplying high quality drug substances for the U.S. market for 50 years. Dipharma holds IP rights on nitisinone, notably in U.S. and Europe. Nitisinone by Dipharma can be stored at room temperature for 24 months and is bioequivalent to Orfadin®.

"We are making very good progress with the global regulatory submissions for our products, and the nitisinone ANDA submission in USA is a key milestone for our company. We will now initiate the selection of a distribution partner for this important market" said Mr. Marc-Olivier Geinoz, CEO of Dipharma.

Nitisinone is used to treat adult and pediatric patients with a confirmed diagnosis of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restrictions. Since its use as the first-line treatment of HT-1, nitisinone has replaced liver transplantation for this rare condition. Nitisinone Dipharma has already been approved and launched in several European countries.

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

Orfadin® is a registered trademark of Swedish Orphan Biovitrum/SOBI. In the United States of America Orfadin® was first approved in January 2002 for the treatment of HT-1.