PRESS RELEASE

Stockholm, Sweden, 17 May 2017

Orfadin® capsules approved in the Kingdom of Saudi Arabia for the treatment of hereditary tyrosinemia type 1

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that the Saudi Food and Drug Administration (SFDA) has approved Orfadin® (nitisinone) capsules in all strengths (2 mg, 5 mg, 10 mg and 20 mg) for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. HT-1 is a progressive, rare genetic disease that may result in liver and kidney complications and in most cases fatal if untreated. In the most common form of the disease, symptoms arise within the first six months of the child's life.

“We are very pleased that Orfadin has received approval from the SFDA. The Kingdom of Saudi Arabia is the largest market in the Middle East, and our focus will now be to ensure timely and sustainable access to treatment for people living with HT-1 on this market”, says Ahmad Abu-Dahab, Regional Director Middle East & Turkey.

“Sobi’s vision is to support that patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives no matter where in the world they live. This approval is another important step on this journey,” says Bodil Jonason, Vice President Commercial Operations and Head of Global Brands at Sobi.

About Orfadin®

People with hereditary tyrosinemia type 1 (HT-1) have problems breaking down an amino acid called tyrosine. Toxic by-products are formed and accumulate in the body, which can cause liver, renal and neurological complications. Approximately 1,000 persons worldwide are identified as living with HT-1 today.

Orfadin® (nitisinone) blocks the breakdown of tyrosine, thereby reducing the amount of toxic tyrosine by-products in the body. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down. Orfadin is a proprietary product and is developed by and made available globally by Sobi.

Before Orfadin became available, the survival rate in HT-1 was 29 per cent after two years for children who developed symptoms before two months of age. [1] After the introduction of Orfadin, the survival rate is 93 per cent after two years in patients with treatment initiation before two months of age.[2]

[1] van Spronsen FJ, Thomasse Y, Smit GP, et al. Hepatology. 1994;20(5):1187-1191

[2] Orfadin EPAR: Product information 26/01/2017

Swedish Orphan Biovitrum AB (publ)
Postal address: SE-112 76 Stockholm, Sweden
Phone: +46 8 697 20 00 | www.sobi.com

For full European prescribing information, please visit the EMA website. For full US prescribing information please see www.orfadin.com

About Sobi™

Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2016 Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

For more information please contact

Media relations

Linda Holmström, Senior Communications Manager

T: + 46 708 73 40 95, + 46 8 697 31 74

linda.holmstrom@sobi.com

Investor relations

Jörgen Winroth, Vice President, Head of Investor Relations

T: +1 347 224 0819, +1 212 579 0506, +46 8 697 2135

jorgen.winroth@sobi.com