PRESS RELEASE

Stockholm, Sweden, 7 March 2017

FDA approves in-use storage at room temperature for Orfadin® capsules

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that FDA has approved in-use storage at room temperature (25°C or less) for up to 45 days for all strengths of Orfadin® capsules (2 mg, 5 mg, 10 mg and 20 mg). The FDA approval follows the already existing approval by the European Medicines Agency (EMA) for in-use storage at room temperature. In addition to this, FDA also approved an extended shelf life for Orfadin capsules 20 mg, from 24 to 36 months.

Orfadin is approved for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

"The approval for increased shelf life and extended out-of-refrigeration time may help make Orfadin an even more flexible treatment option," says Jon Miller, President of the Network of Tyrosinemia Advocates (NOTA). "Continued treatment improvements like this may help to lessen the burden of HT-1 for patients and their families."

"Sobi has a long-term commitment to improve the lives of people living with HT-1, and the modified storage recommendation is a further step in 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]

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

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

[2] Orfadin EPAR: Product information 25/07/2013 Orfadin -EMEA/H/C/000555 -IB/0045

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