PRESS RELEASE

Stockholm, Sweden, 2 February 2017

Sobi obtains approval from the European Commission for new dosing frequency of Orfadin®

Swedish Orphan Biovitrum International AB (publ) (Sobi™) has received confirmation by the European Commission (EC) approving a reduced dosing frequency for Orfadin® (nitisinone) from twice daily to once daily, in people with hereditary tyrosinemia type 1 (HT-1) with a body weight >20 kg.

"Sobi has a long-term commitment to improve the lives for people affected by hereditary tyrosinemia type 1, and the above modified dosing regimen is a further step in this journey", says Milan Zdravkovic, Senior Vice President, Chief Medical Officer, and Head of Research & Development at Sobi.

The approval is based on the results of a clinical study in 18 people with HT-1, comparing a four week once-daily and four week twice daily dosing regimen. The study showed comparable blood-levels of nitisinone, as well as safety and efficacy for these two regimens. There was insufficient data (few people below 20 kg bodyweight were enrolled in the study) to be able to compare the two regimens in people below 20 kg.

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.

[1] van Spronsen FJ, Thomasse Y, Smit GP, et al. Hepatology. 1994;20(5):1187-1191
[2] Orfadin Product monograph 12/12/2016 (Submission Control No: 193226)

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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 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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