PRESS RELEASE

Stockholm, Sweden, 5 September 2017

Sobi receives approval from the FDA for once-daily dosing frequency of Orfadin® for the treatment of HT-1

Swedish Orphan Biovitrum AB (publ) (Sobi™) has received approval from the U.S. Food and Drug Administration (FDA) for a reduced dosing frequency for Orfadin® (nitisinone) from twice daily to once daily in patients 5 years of age and older. The approval is based on the results of a clinical study in 16 people with hereditary tyrosinaemia type 1 (HT-1), comparing a four week once-daily and four week twice daily dosing regimen.

Orfadin is approved in combination with dietary restriction of tyrosine and phenylalanine for people with HT-1, a rare genetic disorder that can cause liver, renal and neurological complications. The reduced dosing frequency is approved for use in patients 5 years of age and older who have undetectable serum and urine succinylacetone concentrations after a minimum of 4 weeks on a stable dosage of nitisinone. A once-daily dosing option was also approved by the European Commission in the beginning of 2017.

“We are very happy to receive the approval by the FDA of the new dosing frequency for Orfadin. Orfadin is the first nitisinone product approved for once daily use in the US. This is an important step towards reducing the treatment burden of people with HT-1 and it follows Sobi’s introduction of Orfadin 20mg capsules and Orfadin oral suspension,” says Milan Zdravkovic, Senior Vice President, Chief Medical Officer, and Head of Research & Development at Sobi.

About Orfadin®

People with hereditary tyrosinaemia 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 and made available globally by Sobi.

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

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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 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.

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