PRESS RELEASE

Stockholm, Sweden, 4 January 2017

Health Canada approves Orfadin® capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1)

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that Health Canada has approved Orfadin® (nitisinone) capsules for the treatment of hereditary tyrosinaemia 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.

Orfadin capsules will now be available in Canada in a wide range of dosing options; 2mg, 5mg, 10mg and 20mg. Sobi is the first company to offer Orfadin® capsules at the 20mg dosage option, which may allow patients to take fewer pills per day.

"Sobi has been committed to supporting the HT-1 community globally for more than two decades, and we were the first to develop this treatment and make it available in Canada through Health Canada's Special Access Programme," says Bob McLay, Vice President, General Manager, Sobi Canada Inc. "This approval is an exciting moment for Sobi, as we continue to develop impactful therapies that meet the needs of patients and healthcare professionals".

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] Today, treatment with Orfadin as an adjunct to dietary restriction as well as early diagnosis and treatment initiation have dramatically improved outcomes for HT-1 patients and their families.

Orfadin is also approved in the US and Europe for the treatment of patients with confirmed diagnosis of HT-1 in combination with dietary restriction of tyrosine and phenylalanine.

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[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 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, 10 per cent of whom live in Canada.

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.

Orfadin in Canada product information can be searched for on Health Canada's Drug Product Database.

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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