PRESS RELEASE

Stockholm, Sweden, 14 July 2016

Health Canada validates Orfadin® capsule filing

Swedish Orphan Biovitrum AB (publ) (Sobi) announced today that Health Canada has initiated review of the application for approval of Orfadin® (nitisinone) capsules for the treatment of hereditary tyrosinaemia type-1 (HT-1). HT-1 is a rare genetic disease that affects infants and children. It is progressive and may result in liver and kidney complications and can be fatal if untreated.

"We are very pleased that the review process for Orfadin capsules in Canada has started. Canada and Quebec is home to 10 per cent of the world's HT-1 population and has been a priority for Sobi since we took direct responsibility for Orfadin in the region. If approved, it will be a major step in ensuring that HT-1 patients throughout Canada could have sustainable access to Orfadin treatment going forward," says Michael Yeh, Head of Global Medical Affairs Core Products at Sobi.

Twenty years ago, before pharmacological treatment was available, fewer than one third of infants diagnosed with HT-1 before two months of age lived past their second birthday.[i] Today, treatment with Orfadin as an adjunct to dietary restriction and early diagnosis have demonstrated improved outcomes for HT-1 patients.[ii]

Orfadin is approved in the US and Europe for the treatment of patients with confirmed diagnosis of hereditary tyrosinaemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. If approved in Canada, the range of dosing alternatives – 2mg, 5mg, 10mg, and 20mg capsules – provides the possibility to personalise treatment for HT-1 patients.

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. In the most common form of the disease, symptoms arise within the first six months of the child's life. 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 is currently available in Canada through the Special Access Programme (SAP) and provided in five dosing alternatives: 2mg, 5mg, 10mg, 20mg capsules and 4mg/ml oral suspension.

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About Sobi™

Sobi™ is an international specialty healthcare company dedicated to rare diseases. Our 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. We also market a portfolio of speciality 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 approximately 700 employees. The share (STO: SOBI) is listed on NASDAQ Stockholm.

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[i] van Spronsen FJ, Thomasse Y, Smit GP, et al. Hepatology. 1994;20(5):1187-1191
[ii] Orfadin EPAR: Product information 25/07/2013 Orfadin -EMEA/H/C/000555 -IB/0045