PRESS RELEASE

Stockholm, Sweden, 15 June 2016

Orfadin® 20 mg capsule approved in the US

Swedish Orphan Biovitrum AB (publ) (Sobi) announced today that the Food and Drug Administration (FDA) has approved a higher strength 20 mg capsule of Orfadin® (nitisinone) 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.

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 of tyrosine and phenylalanine as well as early diagnosis have improved outcomes for HT-1 patients.[ii] Today there are people with HT-1 diagnosed early and started on treatment early in life, growing up to become adults.

Because dosing is adjusted by weight, patients need progressively higher doses as they grow. Sobi has developed the higher capsule strength of 20 mg to support the treatment regimens of adolescent and adult patients that may allow for fewer capsules per dose. This is important because of the chronic nature of their treatment.

“The HT-1 patient journey has driven Sobi’s development of a new strength for Orfadin in order to support sustainable outcomes over a lifetime for HT-1 patients. We are committed to the HT-1 community and are proud to expand the treatment alternatives for this community,” says Michael Yeh, Head of Global Medical Affairs Core Products at Sobi.

Orfadin is approved in the US and several other countries for the treatment of patients with confirmed diagnosis of hereditary tyrosinaemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. Orfadin, together with the appropriate diet, is an essential part of effective HT-1 treatment. In April 2016, Sobi announced the approval of the Orfadin oral suspension in the US, thereby providing the possibility to now personalise treatments with five dosing alternatives: 2mg, 5mg, 10mg, 20mg capsules and 4mg/ml oral suspension.

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.

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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 marketed globally by Sobi. Orfadin is provided in five dosing alternatives: 2mg, 5mg, 10mg, 20mg capsules and 4mg/ml oral suspension. For full US prescribing information, please see www.orfadin.com.

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