PRESS RELEASE

Stockholm, 26 April, 2016

Orfadin® Oral Suspension approved in the US

Swedish Orphan Biovitrum AB (publ) (Sobi™) announced today that the US Food and Drug Administration (FDA) has as of 22 April 2016, approved Orfadin® (nitisinone) Oral Suspension for the treatment of hereditary tyrosinaemia type-1 (HT-1) in combination with dietary restriction of tyrosine and phenylanine. 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.[1] Today, treatment with Orfadin as an adjunct to dietary restriction as well as early diagnosis have improved outcomes for HT-1 patients.[2] Orfadin is approved in the US and several other countries for the treatment of patients with HT-1 in combination with dietary restriction of tyrosine and phenylalanine.

“The HT-1 patient journey – from early screening and diagnosis, to improved medical care associated with continuous higher survival rates – has driven Sobi’s commitment to develop new strengths and formulations for Orfadin to continually meet the medical needs of HT-1 patients”, says Michael Yeh, Vice President Medical Affairs.

Maintaining a strong patient-centric approach is central, and Sobi is continuously developing initiatives based on the expressed needs of patients, healthcare providers and healthcare professionals. As more countries introduce new-born screening for HT-1, infants are diagnosed earlier in life. Dosing is adjusted by weight and as babies grow month by month, their dose is adjusted continuously. The new oral suspension of Orfadin aims to facilitate administration, especially in paediatric use.

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. Orfadin® (nitisinone) blocks the breakdown of tyrosine, thereby reducing the amount of toxic by-products in the body. In the most common form of the disease, symptoms arise within the first six months of the child's life. Patients must maintain a special diet in combination with Orfadin treatment as tyrosine is not adequately broken down. Approximately 1,000 persons are identified as living with HT-1 today. Orfadin is a proprietary product and is developed by and marketed globally by Sobi. For full US prescribing information, please see www.orfadin.com.

[1] van Spronsen FJ, Thomasse Y, Smit GP, et al. Hepatology. 1994;20(5):1187-1191

[2] Orfadin EPAR: Product information 25/07/2013 Orfadin -EMEA/H/C/000555 -IB/0045

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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. More information is available on www.sobi.com.

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