

PRESS RELEASE

Stockholm, 19 January 2016



Sobi's Orfadin® oral suspension granted European patent

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi) today announced that the European Patent Office (EPO) has decided to grant a European patent for the Orfadin® (nitisinone) oral suspension formulation, which was approved by the European Commission for the treatment of Hereditary Tyrosinaemia type-1 (HT-1) in 2015. 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.

"Sobi has a long-term commitment to the HT-1 community and work to continuously improve the available treatment options. The oral suspension formulation is a demonstration of this commitment to the needs of the infants and children diagnosed with HT-1 early in life", said Geoffrey McDonough, CEO and President of Sobi. "The oral suspension of Orfadin for paediatric use facilitates dosing accuracy and simplifies ease of use."

Before pharmacological treatment was available, less than one third of infants diagnosed with HT-1 before two months of age lived past their second birthday.ⁱ Treatment with Orfadin combined with dietary restriction of tyrosine and phenylalanine and more widespread new-born screening, leading to early diagnosis have dramatically improved outcomes for HT-1 patients.ⁱⁱ

The patent, granted in January 2016, will confer protection to the Orfadin oral suspension formulation in each contracting and extension state to the European Patent Convention (EPC).

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.

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 for partner companies across Europe, the Middle East, North Africa and Russia. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2014, Sobi had total revenues of SEK 2.6 billion (USD 380 M) and about 600 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

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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 -EMA/H/C/000555 -IB/0045