

PRESS RELEASE

Stockholm, Sweden, 27 November 2017



Sobi receives approval from Health Canada for Orfadin® Oral Suspension for the treatment of HT-1

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi™) has received approval from Health Canada for an oral suspension formulation of Orfadin® (nitisinone). Orfadin is a medicine approved in multiple countries across North America and Europe for use in combination with dietary restriction of tyrosine and phenylalanine in the treatment of hereditary tyrosinaemia type 1 (HT-1), a rare genetic disorder that can cause liver, renal and neurological complications and in most cases is fatal if untreated.

“The introduction of new nitisinone dosing options, such as Orfadin oral suspension, is the result of Sobi listening to feedback from patients and caregivers and continuing to innovate to meet their needs,” says Bob McLay, Vice President and General Manager of Sobi Canada Inc. “In various markets around the world where Sobi has already introduced multiple innovative Orfadin formulations such as Orfadin oral suspension and Orfadin 20 mg capsules, we have seen patients increasingly choose these dosing options over the first-generation capsules, so we are excited to be able to offer a choice to patients in Canada as well.”

Both Orfadin oral suspension and Orfadin 20 mg capsules are available in Canada, as well as the original 2 mg, 5 mg and 10 mg capsules.

About hereditary tyrosinaemia (HT-1)

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.

About Orfadin®

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 and made available globally by Sobi.

For full European prescribing information, please visit the EMA website. For full US prescribing information please see www.orfadin.com. Full Canadian prescribing information can be found on the [Sobi North America website](#).

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 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

For more information please contact**Media relations**

Linda Holmström, Senior Communications Manager

T: + 46 708 73 40 95, + 46 8 697 31 74

linda.holmstrom@sobi.com

Investor relations

Jörgen Winroth, Vice President, Head of Investor Relations

T: +1 347 224 0819, +1 212 579 0506

jorgen.winroth@sobi.com