### **PRESS RELEASE**

Stockholm, August 22, 2013



## Sobi submits application for Orfadin® oral suspension to EMA

Swedish Orphan Biovitrum AB (publ) (Sobi) announced today that the company's application for Orfadin oral suspension has been validated by the European Medicines Agency (EMA). This new dosage form has been developed to facilitate the ease and accuracy in administration of the desired Orfadin dose to paediatric patients and to increase convenience for the patients and their caregivers.

"We are glad that our application for the Orfadin oral suspension has been accepted by EMA", said Birgitte Volck, Senior Vice President and Chief Medical Officer at Sobi. "The liquid formulation of Orfadin will facilitate precise dosing for children and should also help increase adherence which is key in any successful treatment."

The oral suspension is included in a Paediatric Investigation Plan (PIP) agreed with EMA in March 2012.

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### About Orfadin

Orfadin is used for the treatment of hereditary tyrosinemia type 1 (HT-1), a rare genetic disorder which can cause liver failure, kidney dysfunction and neurological problems.

#### **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 inflammation and genetic diseases, with three late stage biological development projects within haemophilia and neonatology. We also market a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2012, Sobi had total revenues of SEK 1.9 billion (€ 215 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at <a href="https://www.sobi.com">www.sobi.com</a>.

# For more information – not for publication

Media relations
Oskar Bosson, Head of Communications
T: +46 70 410 71 80
oskar.bosson@sobi.com

Investor relations
Jörgen Winroth, Vice President, Head of Investor Relations
T: +1 347-224-0819, +1 212-579-0506, +46 8 697 2135
jorgen.winroth@sobi.com