

## PRESS RELEASE

Stockholm, 27 December 2013



### **Sobi to temporarily withdraw New Drug Application for Orfadin® oral suspension in the US**

Swedish Orphan Biovitrum AB (publ) (Sobi) announced today its decision to withdraw the company's New Drug Application for an oral suspension of Orfadin in the US. The decision to withdraw the current application is based on a request for further information by the US Food and Drug Administration (FDA) regarding the usability by the intended user population of the Orfadin oral suspension and the oral syringe to be included in the package.

Sobi will discuss a re-submission date for the Orfadin oral suspension with the FDA in Q1 2014.

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#### **About Orfadin**

Orfadin is used for the treatment of hereditary Tyrosinaemia 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 [www.sobi.com](http://www.sobi.com)

#### **For more information – not for publication**

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