#### SWEDISH ORPHAN BIOVITRUM

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# Swedish Orphan Biovitrum has decided to move Kiobrina® into phase III development

Stockholm, Sweden – April 21, 2010 – Swedish Orphan Biovitrum (STO: BVT) today announced the results from the second Kiobrina<sup>®</sup> clinical phase II study. The study demonstrated an improvement in preterm infant growth velocity when Kiobrina<sup>®</sup> was administered in pasteurized breast milk. As a consequence of this outcome and the previously announced positive results from a phase II study in preterm infant formula, Swedish Orphan Biovitrum has taken the decision to move Kiobrina<sup>®</sup> into phase III development.

The combined results of the two clinical studies showed a statistically significant increase (p<0.001) in growth velocity, which is a medically relevant parameter. The safety profile was comparable to that of placebo and no drug-related serious adverse events were reported. The results from these studies will be published during 2010, starting with a presentation of the results from the first clinical study with infant formula at "The Power of Programming 2010. International conference on developmental origins of health and disease" in Munich, Germany on May 6-8, 2010.

"Kiobrina holds a great opportunity to fill a substantial medical need in neonatal care. The result from our phase II program is an important step towards a valuable product that will support preterm infants in their growth and development" said Peter Edman, CSO of Swedish Orphan Biovitrum Group.

"This is yet another exciting late stage development progress for Swedish Orphan Biovitrum with a potential of creating a unique medical value in neonatal care as well as business growth for our company" said Martin Nicklasson, CEO.

#### **About Kiobrina**

Kiobrina is a recombinant human bile-salt-stimulated lipase (rhBSSL) developed by Swedish Orphan Biovitrum, aiming to improve growth and development in preterm infants receiving pasteurized breast milk and/or infant formula. The rationale for adding rhBSSL to pasteurized breast milk or infant formula is to restore the natural lipase activity level that is either lost on pasteurization or totally absent in formula.

The phase II Kiobrina program was designed as two parallel prospective randomized double-blind crossover studies where Kiobrina®, or placebo, was administered in pasteurized milk, or preterm infant formula, during one week of treatment. All infants were born before week 32 of gestational age. The objectives were to study the lipid absorption, growth velocity, safety and tolerability.

#### **About Swedish Orphan Biovitrum**

On January 14, 2010, Biovitrum AB (publ) completed the acquisition of Swedish Orphan International Holding AB and created Swedish Orphan Biovitrum – a leading company focused on treatment of rare diseases.

Swedish Orphan Biovitrum is a Swedish based specialty pharmaceutical company with an international market presence. The company is focused on providing and developing orphan and niche specialist pharmaceuticals to patients with high medical needs. The portfolio consists of about 60 marketed products and an emerging late stage clinical development pipeline within rare diseases. Swedish Orphan Biovitrum has pro-forma revenues 2009e of about 2 BSEK and approximately 500

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employees. The head office is located in Sweden and the share (STO: BVT) is listed on NASDAQ OMX Stockholm. For more information please visit www.biovitrum.com.

## For more information please contact: Swedish Orphan Biovitrum:

Peter Edman, CSO Phone. +46 8 697 21 77

Erik Kinnman, EVP Investor Relations Phone: +46 73 422 15 40

erik.kinnman@biovitrum.com

Martin Nicklasson, CEO Phone: +46 8 697 20 00

The clinical phase II studies have been carried out partially with research funding from the European Community's Sixth Framework Program (The Early Nutrition Programming Project, <a href="www.metabolic-programming.org">www.metabolic-programming.org</a>). The press release reflects only the author's views and does not necessarily reflect the views of the European Community or European Commission or their future policy, and they are not liable for any use that may be made of the information contained herein. The information in this document is provided as is and no guarantee or warranty is given that the information is fit for any particular purpose. The user thereof uses the information at its sole risk and liability.

Swedish Orphan Biovitrum may be required to disclose the information provided herein pursuant to the Swedish Securities Markets Act. The information was provided for public release on April 21, 2010 at 8:30 a.m. CET.