PRESS RELEASE

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First patient enrolled in the Kiobrina® phase III study

The first patient has been enrolled in the phase III study with Kiobrina® (rhBSSL) which is designed to evaluate efficacy, safety and tolerability of Kiobrina® in the treatment of preterm infants. Kiobrina® is a recombinant produced human bile-salt stimulated lipase (rhBSSL) developed by Sobi to improve growth in preterm infants who receive pasteurized breast milk or infant formula.

The phase III study is a multicenter, double- blind, placebo-controlled study where preterm infants younger than 32 weeks of gestational age are randomized to receive rhBSSL or placebo added to preterm formula or pasteurized human milk for 4 weeks to demonstrate improved growth velocity. After treatment, there is a follow up period of 1 year. The trial is expected to enroll patients in 70 centers in 11 European countries.

The objective of this phase III study is to confirm the results from two previous phase II studies with Kiobrina® (rhBSSL) administered to either formula or pasteurized milk, respectively. The combined results from the phase II studies showed a statistically significant increase in growth velocity and uptake of long chain polyunsaturated fatty acids such as DHA (Docosahexanoic acid) and AA (Arachidonic acid) (omega-3 and omega-6 fatty acids).

“I am very pleased that the first patient is now included in this trial. Kiobrina® is a unique project developed by Sobi with a potential to improve growth and development of preterm infants”, says Peter Edman, Ph.D., Chief Scientific Officer of Sobi.

About Kiobrina®
Native bile-salt-stimulated lipase (BSSL) is a bioactive component of breast milk important for fat digestion in preterm infants. Kiobrina® is a recombinant human lipase (rhBSSL) with the same amino acid sequence and properties as the native BSSL. The rationale for adding rhBSSL to pasteurized breast milk or infant formula is to restore the natural lipase activity level that is either lost in pasteurization of breast milk or totally absent in formula and thereby improve growth velocity in preterm infants.

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About Swedish Orphan Biovitrum (Sobi)
Sobi is a leading European specialty pharmaceutical company focused on providing and developing specialty pharmaceuticals for patients with rare diseases and significant medical needs. The portfolio comprises about 60 marketed products, as well as projects in late clinical phase. Key therapeutic areas are hematological diseases, autoimmune diseases, hereditary metabolic disorders and therapeutic oncology. In 2010 Sobi had revenues of SEK 1.9 billion and approximately 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. For more information please visit www.sobi.com

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