SWEDISH ORPHAN BIOVITRUM

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Swedish Orphan Biovitrum updates European Kepivance® label

Stockholm, Sweden – March 23, 2010 – Swedish Orphan Biovitrum (STO: BVT) has submitted new data to the Committee for Medicinal Products for Human Use (CHMP), which adopted a positive opinion recommending a variation to the terms of the marketing authorisation for Kepivance®. The new label with an updated SmPC will be implemented after the European Commission has approved the CHMP recommendation.

The pivotal trial published in 2005 where a combination of irradiation and chemotherapy was used, demonstrated Kepivance® to be efficacious in oral mucositis. The now initiated variation is based on the results from of a recently completed clinical trial, which at the time of the Marketing Authorization, was requested by European Medicines Agency (EMA). The study looked at the effect of Kepivance® when one type of chemotherapy-only was used before conditioning preceding hematopoietic stem cell transplantation. In the present study, where multiple myeloma patients received high-dose melphalan (chemotherapy), treatment with Kepivance® did not demonstrate a difference in the maximum severity of oral mucositis compared to placebo.

The new European therapeutic indication proposed by the CHMP to the EU Commission reads: Kepivance® is indicated to decrease the incidence, duration and severity of oral mucositis in patients with hematological malignancies receiving myeloablative radiochemotherapy associated with a high incidence of severe mucositis and requiring autologous hematopoietic stem cell support.

Kennet Rooth, Swedish Orphan Biovitrum Executive Vice President responsible for Sales and Marketing emphasized that Kepivance® is the only drug approved for the prevention of oral mucositis in Europe and the new label now will be closely aligned with the recommendations by leading professional associations such as the European Society for Medical Oncology (ESMO) to use Kepivance® to prevent oral mucositis only in patients with hematological malignancies receiving radiochemotherapy preceding autologous hematopoietic stem cell transplantation.

About Kepivance® (palifermin)
Information about Kepivance® can be found at : http://www.kepivance.com/

Healthcare professionals should refer to national labeling texts, and not the information above.

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 2009 of about 2 BSEK and approximately 500 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:

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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 March 23, 2010 at 8:30 a.m. CET.