



## **Gentium Appoints Swedish Orphan Biovitrum AB as Exclusive Distributor of Defibrotide in Nordic and Baltic Territories**

VILLA GUARDIA (COMO), Italy, January 9 2012, (GLOBE NEWSWIRE) -- Gentium S.p.A. (NASDAQ: GENT) announced the appointment of the Swedish Orphan Biovitrum A.B., (Sobi) (NASDAQ OMX STO: SOBI) as the exclusive distributor of Defibrotide in the following territories: Sweden, Denmark, Norway, Iceland, Finland, Latvia, Lithuania and Estonia. Under the terms of the agreement, which is valid for 10 years, Sobi will be responsible for managing named-patient requests and achieving price and reimbursement approvals in these territories. Following regulatory approval to market Defibrotide, if any, Sobi will be responsible for sales, marketing and local medical affairs activities in the territories.

Commenting on the appointment of Sobi, Adrian Haigh, Senior Vice President of Commercial Operations said, "We are pleased to have established a long-term relationship with Sobi for the Nordic and Baltic territories, which is consistent with our overall commercial strategy to partner with strong local distributors. Sobi has unparalleled experience in managing orphan drugs and an established expertise in the area of stem cell transplantation."

"We are looking forward to the partnership with Gentium and the growth potential that Defibrotide will add to our specialty distribution portfolio. In addition, Defibrotide has a strong strategic fit with our current hematology portfolio, in particular with Kepivance®, targeting patients undergoing stem-cell transplantation," said Anders Edvell, VP, Marketing & Sales at Sobi.

### **About VOD**

Veno-occlusive disease is a potentially life-threatening condition, which typically occurs as a significant complication of stem cell transplantation. Certain high-dose conditioning regimens used as part of stem cell transplantation can damage the lining cells of hepatic blood vessels and so result in VOD, a blockage of the small veins of the liver that leads to liver failure and can result in significant dysfunction in other organs such as the kidneys and lungs (so-called severe VOD). SCT is a frequently used treatment modality following high-dose chemotherapy and radiation therapy for hematologic cancers and other conditions in both adults and children. There is currently no approved agent for the treatment or prevention of VOD in the US or the EU.

### **About Defibrotide**

Defibrotide has the potential to become the first drug approved for the prevention and treatment of hepatic veno-occlusive disease (VOD) a serious and potentially fatal complication of hematopoietic stem-cell transplantation (HSCT). The efficacy of Defibrotide to treat hepatic VOD in HSCT patients is supported by data from a multi-center Phase 3 historically controlled trial, evaluating Defibrotide for the treatment of severe VOD (patients with VOD and multi-organ failure), a Phase 2 dose finding study, and interim data reported from the ongoing Phase 3 expanded access U.S. Treatment IND program in patients with severe hepatic VOD. Additional data include a Phase 3 randomized controlled study of Defibrotide in the prevention of hepatic VOD in pediatric HSCT patients. Defibrotide has generally been well-tolerated in the clinical setting, and results in more than 1,300 patients to date have shown that generally Defibrotide does not appear to increase the risk of complications in HSCT patients.

### **About Gentium**

Gentium S.p.A., located in Como, Italy, is a biopharmaceutical company focused on the development and manufacture of drugs to treat and prevent a variety of diseases and conditions, including vascular diseases related to cancer and cancer treatments. Defibrotide, the Company's lead product candidate, is an investigational drug that has been granted Orphan Drug status by the U.S. FDA and Orphan Medicinal Product Designation by the European Commission both to treat and to prevent VOD and Fast Track Designation by the U.S. FDA to treat VOD. Gentium submitted the MAA for Defibrotide to the EMA in May 2011 and the CHMP issued the 120 day List of Questions in September 2011. Gentium anticipates responding to these questions during the first quarter of 2012. The CHMP review of the MAA will resume with Day 121 on receipt of Gentium's responses.

## **About Swedish Orphan Biovitrum (Sobi)**

Swedish Orphan Biovitrum (Sobi) is a leading integrated biopharmaceutical company dedicated to bringing innovative therapies and services to improve the health of rare disease patients and their families. The company has three business lines: a core product portfolio including 5 proprietary medicines in the core therapeutic areas of Inflammation and Genetics & Metabolism, a Specialty Distribution Portfolio of 50 marketed products, and a GMP biologics facility. Sobi has three protein therapy projects in late stage clinical development– Kiobrina, an enzyme replacement therapy to prevent growth restriction of prematurity in infants, and long acting coagulation factors 8 and 9 for Hemophilia A and B in collaboration with Biogen Idec. In 2010 Sobi had revenues of SEK 1.9 billion and 500 employees. The share (NASDAQ OMX STO: SOBI) is listed on OMX NASDAQ Stockholm. More information is available at [www.sobi.com](http://www.sobi.com).

## ***Cautionary Note Regarding Forward-Looking Statements***

*This press release contains "forward-looking statements." In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of these terms and other comparable terminology. These statements are not historical facts but instead represent the Company's belief regarding future results, many of which, by their nature, are inherently uncertain and outside the Company's control. It is possible that actual results, including with respect to the possibility of any future regulatory approval, may differ materially from those anticipated in these forward-looking statements. For a discussion of some of the risks and important factors that could affect future results, see the discussion in our Form 20-F filed with the Securities and Exchange Commission under the caption "Risk Factors."*

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