



PHARMING

SANTARUS AND PHARMING ANNOUNCE RECEIPT OF FDA REFUSAL TO FILE LETTER FOR RHUCIN BIOLOGICS LICENSE APPLICATION

SAN DIEGO and LEIDEN, The Netherlands (February 28, 2011) – Specialty biopharmaceutical company Santarus, Inc. (NASDAQ: SNTS) and biotech company Pharming Group NV (NYSE Euronext: PHARM) today announced the receipt of a “refusal to file” letter from the U.S. Food and Drug Administration (FDA) for the RHUCIN® (recombinant human C1 inhibitor) Biologics License Application (BLA) submitted by Pharming. In the letter the FDA indicated that the BLA was not sufficiently complete to enable a critical medical review.

In reaching its conclusion, the FDA indicated that the previously conducted studies evaluating RHUCIN for the treatment of acute attacks of Hereditary Angioedema (HAE) did not provide data for a sufficient number of subjects to support the proposed dose of 50 U/kg and lacked prospective validation of the visual analog scale used in measuring the clinical effects of RHUCIN. The FDA also provided other comments on the prior clinical studies and indicated that they will provide additional feedback on the design of the ongoing Phase IIIb clinical study, which had been initiated based on previous discussions with the FDA. In addition, the FDA requested that the results of the Phase IIIb clinical study be included in any future BLA submission for RHUCIN.

The FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission, which occurred in late December 2010. Both companies intend to meet with the FDA at the earliest opportunity to discuss the issues raised in the FDA letter and to reach a more comprehensive understanding of what would be required for the BLA to be accepted for review.

Santarus has licensed certain exclusive rights from Pharming to commercialize RHUCIN in North America for the treatment of acute attacks of HAE and other future indications. Under the terms of the license agreement, Pharming is responsible for conducting and paying for the current Phase IIIb clinical study with RHUCIN in the treatment of acute attacks of angioedema in patients with HAE.

About RHUCIN (RUCONEST in European countries) and Hereditary Angioedema

RHUCIN (INN conestat alfa) is a recombinant version of the human protein C1 inhibitor (C1INH). RHUCIN is produced through Pharming's proprietary technology in milk of transgenic rabbits and in Europe is approved under the name RUCONEST for treatment of acute angioedema attacks in patients with HAE. RHUCIN was granted orphan drug designation for the treatment of acute attacks of HAE, a genetic disorder in which the patient is deficient in or lacks a functional plasma protein C1 inhibitor, resulting in unpredictable and debilitating episodes of intense swelling of the extremities, face, trunk, genitals, abdomen and upper airway. The frequency and severity of HAE attacks vary and are most serious when they involve laryngeal edema, which can close the upper airway and cause death by asphyxiation. According to the U.S. Hereditary Angioedema Association, epidemiological estimates for HAE range from one in 10,000 to one in 50,000 individuals.

About Pharming Group NV

Pharming Group NV is developing innovative products for the treatment of unmet medical needs. RUCONEST™ (RHUCIN® in non-European territories) is a recombinant human C1 inhibitor approved for the treatment of angioedema attacks in patients with HAE in all 27 EU countries plus Norway, Iceland and Liechtenstein. The product is also under development for follow-on indications, i.e. antibody-mediated rejection (AMR) and delayed graft function (DGF) following kidney transplantation. Pharming's advanced technologies include innovative platforms for the production of protein therapeutics, technology and processes for the purification and formulation of these products. Additional information is available on the Pharming website, www.pharming.com.

About Santarus

Santarus, Inc. is a specialty biopharmaceutical company focused on acquiring, developing and commercializing proprietary products that address the needs of patients treated by physician specialists. The company's current commercial efforts are focused on GLUMETZA® (metformin hydrochloride extended release tablets) and CYCLOSET® (bromocriptine mesylate) tablets, which are indicated as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Santarus also has a diverse development pipeline with three late-stage product candidates in Phase III clinical programs: ULTESA™ (budesonide MMX®) for induction of remission of active ulcerative colitis, RHUCIN® (recombinant human C1 inhibitor) for treatment of acute attacks of hereditary angioedema and rifamycin SV MMX® for treatment of travelers' diarrhea. In addition, Santarus plans to initiate a Phase I clinical study in March/April 2011 with SAN-300, its anti-VLA-1 antibody, which the company expects to investigate for the treatment of rheumatoid arthritis. More information about Santarus is available on the company's website at www.santarus.com.

Santarus and Pharming caution you that statements included in this press release that are not a description of historical facts are forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Santarus or Pharming that any of its plans or objectives will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Santarus' and Pharming's businesses, including, without limitation: whether the FDA accepts a future BLA submission for RHUCIN and ultimately approves RHUCIN in a timely manner or at all; whether the ongoing Phase IIIb study is completed in a timely manner and provides adequate support for the approval of RHUCIN; whether the FDA's feedback on the design of the Phase IIIb study is received in a timely manner and whether the feedback requires changes to the design of the ongoing study; whether additional clinical studies and/or development programs beyond the ongoing Phase IIIb study are required to support approval of RHUCIN; risks related to the license and supply arrangements between Santarus and Pharming, including the potential for termination of the arrangements; other difficulties or delays in development, testing, manufacturing and marketing of, and obtaining and maintaining regulatory approvals for, Santarus' and Pharming's products; and other risks detailed in prior press releases as well as in public periodic filings with the Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and neither Santarus nor Pharming undertakes any obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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