



## PHARMING

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### SANTARUS AND PHARMING ANNOUNCE RHUCIN POSTER AT AMERICAN ACADEMY OF ALLERGY, ASTHMA & IMMUNOLOGY 2011 ANNUAL MEETING

**SAN DIEGO and LEIDEN, The Netherlands (March 21, 2011)** – Specialty biopharmaceutical company Santarus, Inc. (NASDAQ: SNTS) and biotech company Pharming Group NV (NYSE Euronext: PHARM) today announced new data on 62 patients with Hereditary Angioedema (HAE) who received repeat treatment with the investigational drug RHUCIN® (recombinant human C1 inhibitor) for 168 acute angioedema attacks. The median time to beginning of relief of symptoms across treatments for repeat attacks was approximately 60 minutes with response rates that were consistently 90% or greater. This open-label study was an extension of the randomized, double-blind, placebo-controlled study conducted by Pharming in North America. The findings were presented Sunday, March 20, 2011 in a poster session at the *American Academy of Allergy, Asthma & Immunology (AAAAI) 2011 Annual Meeting* in San Francisco.

“This larger open label experience supports the safety and efficacy results of RHUCIN 50 U/kg for the treatment of HAE attacks as published last year, and also indicates that this profile was sustained with repeated treatments” said Dr. Rienk Pijpstra, Chief Medical Officer at Pharming.

The poster, *Clinical outcomes with recombinant human C1 inhibitor in the repeat treatment of acute attacks of hereditary angioedema in North American patients* (B Zuraw, et al) summarizes an open-label clinical study that was conducted to assess the safety and efficacy of RHUCIN in the repeat treatment of acute attacks of HAE in abdominal, peripheral, oro-facial-pharyngeal and/or laryngeal and genito-urinary anatomical locations. Time to beginning of relief was assessed by patients using a 100 mm visual analog scale (VAS). Of the 168 attacks, 90% were treated with a single dose of 50 U/kg of RHUCIN. More than 90% of the attacks responded within four hours of treatment. In addition, there were no relapses of attacks (defined as symptom recurrence within 24 hours of treatment) following treatments.

In the safety analysis of the adverse events (AEs), 39 (63%) of the patients reported at least one AE; most of the AEs were considered mild to moderate in severity and 7 patients experienced an AE that was considered severe. None of the AEs were considered to be probably or definitely related to the study drug. The overall incidence of AEs was similar to those in the placebo groups in previously conducted clinical studies with RHUCIN. The frequency of adverse events did not increase upon repeat administrations. Anti-C1 inhibitor antibody results above the assay cut-off were sporadic and transient and did not correlate with repeated treatment or time since last treatment. No neutralizing antibodies were detected. Occasional presence of anti-C1 inhibitor or anti-host related impurities (HRI) antibodies was not associated with adverse events.

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. Pharming is currently conducting a

Phase IIIb clinical study with RHUCIN for 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](http://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: 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 to other earlier-stage development programs. More information about Santarus is available on the company's website at [www.santarus.com](http://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 ongoing Phase IIIb study for RHUCIN is completed in a timely manner and provides adequate support for the approval of RHUCIN; 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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