## PHARMING AND SANTARUS ANNOUNCE INITIATION OF PHASE IIIB CLINICAL STUDY WITH RHUCIN IN ACUTE HEREDITARY ANGIOEDEMA

Leiden, The Netherlands, February 22, 2011. Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) and San Diego based specialty biopharmaceutical company Santarus, Inc. (NASDAQ: SNTS) today announced that Pharming has begun an international, multicenter, randomized, placebocontrolled Phase IIIb clinical study evaluating the investigational drug RHUCIN® (recombinant human C1 inhibitor) for the treatment of acute attacks of angioedema in patients with Hereditary Angioedema (HAE). Pharming expects to enroll approximately 50 patients in the study which may provide additional data, if required by the U.S. Food and Drug Administration (FDA), in support of an approval for RHUCIN at the 50 U/kg dose. Data from the study will also be used to provide additional validation of the visual analog scale used in measuring the clinical effects of RHUCIN. The study is expected to be completed in 12 to 18 months.

The safety and efficacy of RHUCIN for the treatment of HAE attacks were previously evaluated in two randomized placebo-controlled studies and four open label treatment studies. Both placebo-controlled clinical studies showed statistically significant and clinically relevant improvement in the primary endpoint of time to beginning of relief of symptoms at RHUCIN dosage strengths of 50 U/kg and 100 U/kg compared to placebo. In October 2010, Pharming received Marketing Authorization in the European Union for RUCONEST™ (RHUCIN in non-European territories) for the treatment of acute angioedema attacks in patients with HAE. Pharming submitted a Biologics License Application (BLA) for RHUCIN to the FDA in late December 2010. In total, the BLA dossier included nine clinical studies covering 714 administrations in 190 subjects.

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 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 the milk of transgenic rabbits and in Europe is approved under the name RUCONEST for treatment of acute angioedema attacks in patients with HAE. The FDA has granted Orphan Drug Status to RHUCIN 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. Additional information is available on the international patient association's website, www.haei.org.

## **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, rifamycin SV MMX® for treatment of travelers' diarrhea and RHUCIN® (recombinant human C1 inhibitor) for treatment of acute attacks of hereditary angioedema. In addition, Santarus plans to initiate a Phase I clinical study in late 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. These forward-looking statements include statements regarding the potential attributes of RHUCIN, its potential to treat acute HAE or other indications and the potential timing for completion of the Phase IIIb clinical study. 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: risks related to the timing and success of the Phase IIIb study and other development programs relating to RHUCIN; whether the FDA accepts the BLA submission for RHUCIN and approves RHUCIN in a timely manner or at all; whether, based on prior input from the FDA, the FDA requires completion of the Phase IIIb study prior to accepting the BLA submission for RHUCIN or as a precondition to approval of RHUCIN; Santarus' ability to generate market demand and sales of RHUCIN, if approved; competition from other products, unexpected adverse side effects or inadequate therapeutic efficacy of RHUCIN; the ability to ensure continued supply of RHUCIN; the scope and validity of patent protection or other regulatory exclusivity for 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.

Santarus® and ULTESA™ are trademarks of Santarus, Inc. GLUMETZA® is a trademark of Biovail Laboratories International S.r.I. licensed exclusively in the United States to Depomed, Inc. CYCLOSET® is a trademark of VeroScience LLC. MMX® is a trademark of Cosmo Technologies Limited. RHUCIN® and RUCONEST™ are trademarks of Pharming Group NV.

Contact:

Pharming

Karl Keegan, Chief Financial Officer, T: +31 (0)71 52 47 181 or +31 (0)6 3168 0465

Santarus

Martha L. Hough, VP Finance & Investor Relations, T: +1 (858) 314-5824

Debra P. Crawford, Chief Financial Officer, T: +1 (858) 314-5708