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Pharming and Santarus Announce Special Protocol Assessment (SPA) Agreement with FDA for Rhucin® Phase III clinical study

LEIDEN, The Netherlands and SAN DIEGO, August 4, 2011. Biotech company Pharming Group NV (NYSE Euronext: PHARM) and specialty biopharmaceutical company Santarus, Inc. (NASDAQ: SNTS) today announced that they have reached agreement with the U.S. Food and Drug Administration (FDA) on the design of a Phase III clinical study with the investigational drug RHUCIN® (recombinant human C1 inhibitor) under the Special Protocol Assessment (SPA) process that is intended to support the submission of a Biologics License Application (BLA).

RHUCIN is being evaluated for the treatment of acute attacks of angioedema in patients with Hereditary Angioedema (HAE) in an international, multicenter, randomized, placebo-controlled Phase III study at a dosage strength of 50 U/kg with a primary endpoint of time to beginning of relief of symptoms. The Phase III study was initiated in February 2011, but the FDA subsequently requested modifications to the study protocol.

Following discussions with the FDA and implementation of the Agency's recommended changes to the study protocol, the FDA has confirmed that Pharming's proposed trial design, clinical endpoints and statistical analyses are acceptable to the FDA. As a result of the discussions with the FDA, the changes to the study design include, as previously announced, a modification to the way the primary endpoint will be assessed and an increase in the number of patients from 50 to approximately 75. The protocol will also be changed to allow the introduction of open-label doses of RHUCIN as a rescue medication. The study is still expected to be completed by the third quarter of 2012.

"We are pleased to have reached agreement with the FDA under an SPA on the protocol for the Phase III clinical study to support a BLA for RHUCIN in the U.S. Over the past months we have continued to open additional investigational sites and to screen patients for eligibility who can now be randomized into the amended trial," said Rienk Pijpstra, MD, MBA, Chief Medical Officer at Pharming.

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, a US$10 million milestone is payable to Pharming upon successful achievement of the primary endpoint of the Phase III clinical study.

About the Special Protocol Assessment Process
The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design of proposed protocols that are intended to form the basis for a BLA or New Drug Application (NDA). Final marketing approval depends on the results of efficacy, the adverse event profile

and an evaluation of the benefit/risk of treatment demonstrated in all the data contained in the BLA or NDA submission.

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 has been granted orphan drug designation in the U.S. 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. Santarus' 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, including three investigational drugs 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 at www.santarus.com.

Pharming and Santarus 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 Pharming or Santarus 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 Pharming's and Santarus' businesses, including, without limitation: whether the Phase III study for RHUCIN is completed in a timely manner and provides adequate support for the submission of a BLA and approval of RHUCIN; whether additional clinical studies and/or development programs beyond the Phase III study are required to support submission of a BLA and approval of RHUCIN; risks related to the license and supply arrangements between Pharming and Santarus, 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, Pharming's and Santarus' 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.

MMX® is a trademark of Cosmo Technologies Limited. RHUCIN® and RUCONEST® are trademarks of Pharming Group NV.

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