

## PHARMING AMENDS PHASE III CLINICAL STUDY WITH RHUCIN IN ACUTE HEREDITARY ANGIOEDEMA

**Leiden, The Netherlands, May 5<sup>th</sup>, 2011.** Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) today announced that following discussions with the U.S. Food and Drug Administration (FDA), Pharming and its U.S. commercialization partner, Santarus, Inc. have submitted an amendment to the protocol for the RHUCIN® (recombinant human C1 inhibitor) Phase III clinical study into which the first patient was enrolled in February 2011. The Phase III clinical study is evaluating the investigational drug RHUCIN for the treatment of acute attacks of angioedema in patients with Hereditary Angioedema (HAE). Pharming still anticipates that the Phase III study will be completed within 12 to 18 months from its original initiation.

On March 31<sup>st</sup>, Pharming and Santarus met with the FDA to discuss the FDA refusal to file letter received in February 2011 and to gain further clarification on the protocol for the ongoing study to support the RHUCIN Biologics License Application (BLA). Based on input from the FDA and from the FDA meeting minutes, Pharming and Santarus have now submitted an amendment to the protocol, including an increase of the number of patients from 50 to approximately 75 and a modification to the manner in which the primary endpoint will be assessed. This modification eliminates the need for further validation of the visual analog scale.

"We are pleased to be working closely with the FDA to amend the protocol for the Phase III study, which we believe addresses the issues raised by the agency, and upon successful completion of the study, will provide the additional clinical support requested for our future BLA submission" said Rienk Pijpstra, MD, MBA, Chief Medical Officer at Pharming.

### 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).

*RHUCIN® and RUCONEST™ are trademarks of Pharming Group NV.*

*This press release contains forward looking statements that involve known and unknown risks, uncertainties and other factors, which may cause the actual results, performance or achievements of the Company to be materially different from the results, performance or achievements expressed or implied by these forward looking statements.*

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