

## **EUROPEAN MEDICINES AGENCY REAFFIRMS IMPORTANT HEALTH BENEFITS AND SAFETY OF RUCONEST® FOR PATIENTS WITH HEREDITARY ANGIO-EDEMA**

### **PHARMING LAUNCHES RUCOVITAE™ ON-DEMAND CARE PROGRAMME IN AUSTRIA, GERMANY AND THE NETHERLANDS**

**Leiden, The Netherlands, 07 December 2015** – Pharming Group N.V. (“Pharming”) (Euronext Amsterdam: PHARM) announces that the European Medicines Agency (“EMA”) has recently renewed the marketing authorization for RUCONEST for an unlimited period. RUCONEST, the first and only recombinant (non-blood-derived) C1-esterase inhibitor replacement therapy, was first approved by the EMA in June 2010 for the treatment of acute attacks of Hereditary Angioedema (“HAE”). Such initial marketing authorisation is normally issued initially for five years, and reviewed for extension after these first five years.

The recommendation of the Committee for Medicinal Products for Human Use (CHMP) for renewal of the marketing authorization is based on the positive patient benefit-risk profile for RUCONEST for the treatment of HAE attacks.

In addition, Pharming reports that RUCOVITAE, the Company’s patient support programme, is now available to eligible HAE sufferers in Austria, Germany and the Netherlands. RUCOVITAE aims to provide patients with timely on-demand therapy at their home or other specified location to assist them in dealing with their HAE disease and optimize their HAE treatment. The on-demand, on-location care services are provided in Germany and Austria by homecare organisation Atlantis Healthcare Deutschland GmbH and in the Netherlands by Dutch homecare organisation Eurocept B.V. through their country-wide networks of community-based specialised nurses. Eligible HAE patients can enrol in RUCOVITAE through their physician.

Sijmen de Vries, Pharming’s CEO, commented: “We welcome the positive conclusions reached by the EMA in extending the marketing authorization for RUCONEST. We are also very excited that we have been able to organize and initiate RUCOVITAE. This round-the clock, seven days a week “on-demand, on-location” care programme is accessible for every eligible HAE patient in Austria, Germany and Netherlands. We know that by investing in offering HAE patients such care to treat acute attacks with RUCONEST, we will be able to help them improve their quality of life and limit the impact of HAE on their lives by treating an attack as early as possible.”

#### **About Pharming Group N.V.**

Pharming Group N.V. is developing innovative products for the improved treatment of urgent medical needs. RUCONEST® (conestat alfa) is a recombinant human C1-esterase inhibitor approved for the treatment of angioedema attacks in patients with HAE in the US, Israel and all 28 EU countries as well as Norway, Iceland and Liechtenstein.

RUCONEST® is commercialised by Pharming in Austria, Germany and the Netherlands. RUCONEST® is distributed by Swedish Orphan Biovitrum AB (publ) (SS: SOBI) in the other EU countries and in Azerbaijan, Belarus, Georgia, Iceland, Kazakhstan, Liechtenstein, Norway, Russia, Serbia and Ukraine.

RUCONEST® is partnered with Valeant Pharmaceuticals International, Inc. (NYSE: VRX/TSX: VRX). in North America following the acquisition by Valeant of Salix Pharmaceuticals Ltd.

RUCONEST® is also being investigated in a randomised Phase II clinical trial for prophylaxis of HAE as well as being evaluated for various additional follow-on indications.

Pharming has a unique GMP-compliant validated platform for the production of recombinant human proteins that is capable of producing industrial volumes of high quality recombinant human protein in a more economical way compared to current cell-based technologies. Leads for Enzyme Replacement Therapy (ERT) in Pompe and Fabry diseases are under early evaluation. The platform is partnered with Shanghai Institute of Pharmaceutical Industry (SIPI), a Sinopharm Company, for joint global development of new products. Pre-clinical development and manufacturing will take place at SIPI and are funded by SIPI. Pharming and SIPI plan to use this platform initially for the development of recombinant human Factor VIII for the treatment of Haemophilia A.

For more information, please visit <http://www.pharming.com>

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