

## PHARMING SUBMITS RESPONSE TO QUESTIONS MAA RHUCIN D120 clock stop limited to two months

**Leiden, The Netherlands, March 18, 2010.** Biotech company Pharming Group NV (“Pharming” or “the Company”) (NYSE Euronext: PHARM) today announced that it has submitted its response to the Day 120 List of Questions (LoQ) of the Committee for Medicinal Products for Human Use (CHMP) in regard to its European Marketing Authorization Application (MAA) for Rhucin. In addition, the dossier for marketing authorization of Rhucin for HAE has been filed with the Turkish Ministry of Health and is currently under review.

Pharming submitted the MAA for Rhucin to the European Medicines Agency in September 2009 and the CHMP issued the Day 120 List of Questions on 21 January 2010, which did not contain any ‘major concerns’. Pharming’s submission of responses will result in a clock stop of only two months instead of the usual three months. The CHMP review of the MAA will continue on March 21 (Day 121). Another one month clock stop may be expected at Day 180 of the procedure to permit Pharming to respond to any further questions from the CHMP and, in line with the regulatory timetable, the CHMP will reach its final opinion no later than Day 210. More information on this procedure can be found on [www.ema.europa.eu](http://www.ema.europa.eu).

Dr. Bruno Giannetti, Chief Operations Officer of Pharming, said: “Pharming employees have gone the extra mile to achieve a shorter response time and limiting the clock stop to two months only. We are now anticipating receiving the CHMP opinion in the third quarter of this year.”

Alongside, Pharming’s partner Eczacıbaşı İlaç Pazarlama A.Ş. (Eczacıbaşı Pharmaceuticals Marketing or EIP) has submitted a dossier on Rhucin with the Turkish Ministry of Health. The dossier includes all data from the European MAA. The average review time for the Turkish application is approximately 20 months. The decision to grant a marketing authorization in Turkey is independent of decisions made in the EU or the USA.

### **About Rhucin® and HAE**

Rhucin® (recombinant human C1 esterase inhibitor) is a human protein developed through Pharming’s proprietary technology where the human protein is expressed in milk of transgenic rabbits. Pharming is developing Rhucin® for treatment of patients with acute attacks of Hereditary Angioedema (HAE). HAE is a human genetic disorder caused by a shortage of C1 inhibitor activity and results in an overreaction of the immune system. The disease is characterized by acute attacks of painful and in some cases fatal swelling of several soft tissues (edema), which may last up to five days when untreated. In addition to the life-threatening nature of the disease, quality of life for individuals with the disease may be seriously impaired. Approximately one in 30,000 individuals suffers from HAE and has an average of seven acute attacks per year.

## **About Pharming Group NV**

Pharming Group NV is developing innovative products for the treatment of genetic disorders, ageing diseases, specialty products for surgical indications, and nutritional products. Pharming's lead product Rhucin® for acute attacks of Hereditary Angioedema has passed clinical development stage and the Market Authorization Application is under review with the European Medicines Agency. Prodarsan® is in early stage clinical development for Cockayne Syndrome and lactoferrin for use in food products. The advanced technologies of the Company include innovative platforms for the production of protein therapeutics, technology and processes for the purification and formulation of these products, as well as technology in the field of DNA repair (via DNage). Additional information is available on the Pharming website, <http://www.pharming.com>.

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