PHARMING

# PHARMING PRESENTS POSITIVE RESULTS FROM EUROPEAN PHASE III TRIAL OF RHUCIN®

## *PRIMARY AND SECONDARY ENDPOINTS OF STUDY ACHIEVED*

***Leiden, The Netherlands, August 30, 2007.*** Biotech company Pharming Group N.V. ("Pharming" or "the Company") (Euronext: PHARM) announced today positive safety and efficacy results from its European randomized placebo-controlled Phase III clinical trial of Rhucin® for the acute treatment of Hereditary Angieoedema (HAE). The positive results from an interim analysis of its European randomized placebo-controlled Phase III clinical trial follow earlier studies showing the strong positive effect of Rhucin® coupled to an excellent safety profile.

The Phase III double-blind placebo-controlled study with Rhucin® was conducted at several centres across Europe. The trial assessed the safety and efficacy of Rhucin® in patients who presented with different sites of acute HAE attacks. In the analysis, data were analyzed from the first 28 patients randomized to either Rhucin® or placebo. Patients receiving Rhucin® reported first relief at a median time of 60 minutes compared to 8.5 hours for those patients who received placebo. The primary endpoint, time to beginning of symptom relief, achieved statistical significance with a p-value of 0.0009 using the so-called log-rank test which is a common type of statistical analysis in these studies. Typically, if the p-value is below 0.05, the data are considered to be statistically significant. The result achieved at the primary endpoint was also clinically relevant.

In addition, patients receiving Rhucin® reported minimal symptoms at a median time of 6.1 hours compared with 20.2 hours for patients who received placebo. The secondary endpoint which measured time to minimal symptoms, achieved statistical significance with a p-value of 0.0038. The result achieved at the secondary endpoint was also clinically relevant. The analysis demonstrated that 100% of patients in the Rhucin® group responded to treatment and that all of these patients experienced sustained relief without a relapse of their attack symptoms.

The safety experience from the trial indicates that Rhucin® continues to be very well tolerated and there were no drug-related adverse events reported during this study. The Independent Data Monitoring Committee reviewed these results and recommended that the Company discontinue further randomized treatments for methodological and ethical reasons. Randomized treatments in the trial have now been stopped and the study will be amended so patients may continue to have access to Rhucin® through open-label treatments.

The positive results from the study have been provided to the Committee for Medicinal Products (CHMP) of the EMEA in support of the Marketing Authorization for Rhucin® in Europe. Data from the analysis were also submitted to the FDA in the US, where an independent placebo-controlled randomized clinical trial assessing the safety and efficacy of Rhucin® is expected to be completed in the next few months.

Dr. Bruno Giannetti, Chief Operations Officer of Pharming, commented: "We are extremely pleased with the outcome of this analysis. The data confirm the results obtained in earlier studies and show that Rhucin® is a very fast acting product that we expect to have great therapeutic benefits for HAE patients. Most patients experience a relief of their, often, very painful symptoms often within minutes after the treatment begins. The product also has an excellent safety profile based on the results of various studies in which, in total, well over 100 infusions were given to subjects. Importantly, we have also never observed relapses of the attack. We are confident that the clinical data obtained so far, combined with preclinical and other data as well as our recently obtained-GMP status will form a solid basis for eventual registration of Rhucin® in Europe and elsewhere in order to make the product available for patients who suffer from this severe disease."

A meeting for analysts and press will be held at the offices of Financial Dynamics in London on August 30th at 10:30 am (UK-time) to discuss the results summarized in this press release. Copies of the presentation and the presented data will be available on the company's website at the start of that meeting

**About Rhucin® and HAE**
Rhucin® (recombinant human C1 esterase inhibitor) is a human protein developed through Pharming's proprietary technology in milk of transgenic rabbits. Rhucin® is currently under development 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 the Western world, approximately 1 in 30,000 individuals suffers from hereditary angioedema, having an average of seven acute attacks per year.

Pharming has filed a Marketing Authorization Application for Rhucin® in Europe. Based on the timelines associated with the review of this product, Pharming expects an opinion of the scientific committee of the EMEA later this year. In the USA, Pharming aims to finalize its placebo-controlled randomized clinical trial in the second half of 2007.

**About Pharming Group N.V.**
Pharming Group NV is developing innovative products for the treatment of genetic disorders, specialty products for surgical indications, intermediates for various applications and food products. Pharming has two products in late stage development - recombinant human C1 inhibitor for hereditary angioedema (MAA submitted to EMEA) and human lactoferrin for use in functional foods (GRAS notification filed with FDA). 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 technologies in the field of tissue repair (via its collaboration with Novathera) and DNA-repair (via its acquisition of DNage BV). Additional information is available on the Pharming website, http://www.pharming.com and on http://www.dnage.nl

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