PHARMING

PHARMING SUBMITS MARKETING AUTHORISATION APPLICATION FOR RHUCIN® TO THE EMEA

Leiden, The Netherlands, September 3, 2009. Biotech company Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) today announced that it has submitted the Marketing Authorization Application (MAA) for Rhucin for the treatment of acute attacks of Hereditary Angioedema (HAE) to the European Medicines Agency (EMEA).

In this new MAA, Pharming has followed up on and addressed concerns raised by the CHMP during the former evaluation procedure in 2007. In particular, the size of the clinical database has been significantly expanded, additional clinical efficacy and safety data have been collected and analyzed, and an analysis of immunogenicity data after (repeat) treatment with Rhucin has been completed.

Efficacy of Rhucin was demonstrated in two randomized controlled studies and is supported by four open label studies, including the successful treatment of potentially life-threatening laryngeal attacks. In the placebo controlled clinical studies a total of 70 patients were randomized to Rhucin (100 U/kg or 50 U/kg body weight) or placebo control treatment. Patients with active Rhucin treatment responded rapidly to treatment, with statistically significant and clinically relevant shorter time to onset of relief and time to minimal symptoms compared to placebo. No relapses of attacks were recorded. Superiority over placebo was also consistently supported by exploratory endpoints, sensitivity analyses and subgroup analyses. Additional data on 155 attacks in 79 patients collected in the ongoing open-label studies furthermore confirmed Rhucin's efficacy.

The updated safety dataset comprising 405 administrations in 164 subjects, includes 14 patients with at least five repeat administrations, Rhucin continued to be well tolerated, the adverse event profile observed in the controlled studies, was similar to that of placebo, and there were no significant infusion site reactions such as pain. The immunogenicity analysis of 621 plasma samples covering 217 treatments in 119 patients showed a reassuring immuno-safety profile, without evidence for induction of neutralizing antibodies against Rhucin, nor for induction of allergies.

"The MAA re-submission is a significant milestone in the development of Rhucin and demonstrates our commitment to provide a highly effective therapy for patients living with the burden of Hereditary Angioedema", said Dr. Bruno Giannetti, Chief Operations Officer. "We believe that our new MAA submission addresses all issues that remained after the previous CHMP opinion in 2008. We are convinced that our current clinical database adequately supports the efficacy and safety of Rhucin, in single and repeated use and in all types of acute attacks including laryngeal attacks. Our next focus will be the admission of a Biologic License Application (BLA) for Rhucin in the USA and we will request a pre-BLA meeting by the end of 2009."

Upon receipt of the MAA, the EMEA will validate the dossier and may require additional data, information or clarification before the start of evaluation of the scientific content of the dossier. Once the application is validated, the EMEA starts the Centralised Procedure for scientific evaluation of the MAA by the Committee for Medicinal Products for Human Use (CHMP) according to a standard timetable. At day 120, the CHMP produces a List of Questions to be answered within 3 months by the company. More information on this procedure can be found on http://www.emea.europa.eu/pdfs/human/regaffair/7540106en.pdf and related EMEA documents. The Company will provide further information on progress of the review of the Rhucin MAA dossier at appropriate stages during the process.

Background on Hereditary Angioedema

HAE is a genetic disorder caused by a shortage of C1 inhibitor activity. Approximately one in 30,000 individuals suffers from HAE and has an average of seven acute attacks per year. HAE attacks that are untreated can last up to five days. The disease is characterized by acute attacks of painful swelling of soft tissues (edema), including regions of the skin, the intestine, and the mouth and throat. If the soft tissue of the throat is involved, an attack of angioedema can be fatal. In addition to the life-threatening nature of the disease, quality of life for individuals with the disease may be seriously impaired.

About Pharming Group NV

Pharming Group NV is developing innovative products for the treatment of genetic disorders, ageing diseases, specialty products for surgical indications, intermediates for various applications and nutritional products. Pharming has two products in late stage development - Rhucin® for Hereditary Angioedema and human Lactoferrin for use in food products and one product in early stage clinical development - Prodarsan® for Cockayne Syndrome. 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.

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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