# PHARMING'S C1 INHIBITOR EFFECTIVE IN PREVENTING AMR IN ANIMAL MODEL OF TRANSPLANT REJECTION

**Leiden, The Netherlands, April 1, 2010.** Biotech company Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) announced today publication of preclinical evidence that its recombinant human C1 inhibitor (rhC1INH) was effective in a primate model in preventing antibody-mediated rejection (AMR) following kidney transplantation.

Following transplantation, some patients make specific antibodies against the donor kidney that cause activation of the classical complement system. This process known as antibody-mediated rejection, results in inflammatory damage to the transplanted kidney that can lead to organ failure and graft loss. Over the past decade, AMR has been increasingly recognized as a serious transplantation complication that can lead to loss of the transplanted organ. Current treatments for AMR are non-specific and have suboptimal efficacy.

In the published study, Dr. Gilles Blancho and colleagues from the Institute of Transplantation - Urology - Nephrology (ITUN) in Nantes, France, demonstrated that Pharming's rhC1INH prevented AMR in a baboon AMR model by blocking the activation of the classical complement system in the treated animals, whereas untreated animals developed AMR by the second day following transplantation. Histopathological results indicated that the classical complement pathway was effectively inhibited during treatment as evidenced by the lack of specific complement deposition in the kidney, which is also the hallmark of AMR in humans. The results also confirmed the group's earlier positive findings with rhC1INH at inhibiting cytotoxicity. These results are published in Kidney International (advance online publication, 24 March 2010) by Dr Tillou *et al.* 

"The data we observed in this stringent model of AMR suggest that rhC1INH may be even more efficient in less severe experimental or clinical situations", said Dr. Blancho. "AMR remains an unsolved issue in transplantation and rhC1INH could be an effective complementary treatment for this challenging problem."

"These results support the significant potential for rhC1INH in antibody-mediated rejection, which is a serious transplantation complication", commented Dr. Bruno Giannetti, COO of Pharming. "Earlier this year, preclinical evidence was published indicating rhC1INH could also be effective in preventing delayed graft function following kidney transplantation. We intend to initiate clinical studies in patients for both of these indications later this year."

### **About transplantation**

In the United States alone, over 79,000 patients are waiting for an organ transplant (35,000 in the EU). Each month, nearly 3,000 new patients are added to this waiting list. However, only 25,000 solid organs are available and transplanted each year, including kidney, liver, lung and heart transplants. In addition, complications may arise following organ transplantation, such as antibody-mediated rejection (AMR) and delayed graft function (DGF).

## **PHARMING**

### **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® has completed clinical development for acute attacks of Hereditary Angioedema and a Market Authorization Application is under review with the EMA. Prodarsan® is in early stage clinical development for Cockayne Syndrome and human 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.

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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