

## Prodarsan® granted Orphan Drug designation from FDA

**Leiden, The Netherlands, April 27, 2009.** Biotech company Pharming Group NV (“Pharming” or “the Company”) (NYSE Euronext: PHARM) announced today that its wholly owned subsidiary DNage BV (“DNage”) has received a notice from the US Food and Drug Administration (“FDA”) that its product Prodarsan® has been awarded an Orphan Drug designation for the treatment of Cockayne Syndrome. Prodarsan® is a combination of two small molecules, formulated for oral use, which are believed to reduce the accumulation of DNA-damage, the underlying biochemical cause of Cockayne Syndrome.

Cockayne Syndrome, the initial target of Prodarsan®, is a rare genetic disease in which children suffer from accelerated (or premature) aging, while developing severe aging diseases. Progeria diseases are a group of genetic premature aging diseases which manifest in several forms that are genetically and clinically similar although not identical. Depending on the specific form of the disease, patients have a significantly reduced life expectancy and exhibit many aging-related symptoms early on in their lives. Quality of life for these patients is seriously impaired. Cockayne Syndrome is one of the more common forms of progeria and is characterized, among others, by growth failure, mental retardation, hearing and sight problems and a reduced life expectancy. Currently, no effective therapy for Cockayne Syndrome is available.

DNage has demonstrated that Prodarsan® has significant beneficial effects in animal models for Cockayne Syndrome. Furthermore, it has shown that the product was safe and well-tolerated in a study in human volunteers. In consultation with the FDA, the Company is now preparing to submit an IND (Investigational New Drug) Application that will allow the initiation of additional clinical studies in patients. The Principal Investigator in these planned international studies is Dr. Edward Neilan, Staff Physician at Children's Hospital Boston / Harvard Medical School, a world renowned clinician and researcher in the field of Cockayne Syndrome.

Dr. Neilan commented: “Based on discussions with the FDA and the designation of Prodarsan® as an Orphan Drug, I believe we are making important progress in finding new treatment modalities for this severe disease. My interactions with many patients and their families have convinced me that there is a very strong medical need for new treatments. I look forward to leading the further clinical investigation of this potential new medicine together with several colleagues in the USA and Europe and hope that the promising data in animals and human volunteers will hold up in Cockayne Syndrome patients as well.”

The FDA's Orphan Drug designation is reserved for new therapies being developed to treat diseases or conditions that affect fewer than 200,000 people in the United States. The Orphan Drug designation provides for an accelerated review process, tax benefits, exemption from user fees and a seven-year period of market exclusivity in the US after product approval. The designation is awarded based on an application describing the disease, the product and an extensive outline of the proposed development plan. The application for Prodarsan® was filed by Clinquest, DNage's agent in the USA.

## **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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