PHARMING

Pharming and Shanghai Institute of Pharmaceutical Industry (SIPI) establish strategic collaboration

- . Joint global biologicals development at SIPI using Pharming platform and know- how
 - SIPI to commercialise Ruconest® (conestat alfa) in China

Leiden, The Netherlands and Shanghai, China, July 01, 2013. Biotech company Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) and Shanghai Institute of Pharmaceutical Industry ("SIPI"), a Sinopharm Company, announced today that they have entered into a strategic collaboration for the development, manufacture and commercialisation of new products based on the Pharming technology platform. In addition, Pharming has also granted SIPI an exclusive license to commercialise Ruconest (conestat alfa) in China.

莱顿,荷兰和上海,中国,2013 年 7 月 1 日。生物科技公司 Pharming 集团 NV(简称 "Pharming"或"公司")(纽交所:PHARM)和上海医药工业研究院(简称"SIPI"),国药集团子公司,今天宣布,他们就基于 Pharming 技术平台的新产品研发,生产和商业化达成了战略合作。此外,Pharming 将 Ruconest 的中国商业化的独家许可授予 SIPI。

Under the terms of the agreement, Pharming will transfer the Pharming technology platform and manufacturing know- how to SIPI, such that joint global development for new products will take place at SIPI's facilities in Shanghai and benefit from both the cost advantages of the Pharming platform and the competitive development and manufacturing costs structures at SIPI.

根据该协议的条款,Pharming 公司将 Pharming 技术平台和生产诀窍转让给 SIPI,新产品的全球合作开发将在 SIPI 进行,双方将受益于 Pharming 公司平台的成本优势和 SIPI 有竞争力的研发和生产成本结构。

The first projects to be jointly developed at SIPI will be C1-inhibitor (conestat alfa) and Factor VIII. Under the agreement, SIPI will fund preclinical and manufacturing development.

在 SIPI 联合开发的第一个项目将是 C1-抑制剂(conestat alfa)和凝血因子 VIII。 SIPI 将投资在临床前研究和生产发展阶段。

Pharming will be responsible for obtaining Investigational New Drug (IND) applications from the US Food and Drug Administration (FDA) and/ or a Clinical Trial Application (CTA) from the European Medicines

Agency (EMA); SIPI will be responsible for obtaining a Clinical Trial Permit (CTP) from the China Food and Drug Administration (CFDA) for each of the products.

Pharming 公司将负责从美国食品和药物管理局(FDA)获得新药临床研究申请(IND)和/或从欧洲药品管理局(EMA)获得临床试验申请(CTA); SIPI 将负责从中国食品和药物管理局(CFDA)获得每个产品的临床试验批件(CTP)。

SIPI will fund and be responsible for clinical development in China and Pharming for all clinical development outside of China. Both parties will, wherever possible, coordinate and combine clinical development activities.

SIPI 和 Pharming 公司共同投资,以满足新产品在中国内外的临床研发。双方将尽可能协调和联合进行临床研发活动。

To ensure world- wide commercialisation of the products developed and manufactured by SIPI, product development and manufacturing at SIPI will be implemented under Pharming's fully ICH compliant quality assurance systems, and will be compliant with all CFDA, EMA and FDA regulatory guidelines

为了确保 SIPI 研发和生产的产品在世界各地的商业化,在 Pharming 技术支持的协助下,SIPI 的产品研发和生产将实行 ICH 标准的质量保证体系,以及符合所有 CFDA,EMA 和 FDA 的监管指标

SIPI will have commercialisation rights for the Chinese market for all new products developed; Pharming will retain global rights ex-China.

SIPI 将享有所有新产品的中国市场商品化权利,Pharming 将保留在中国以外的全球权利。

Over the past three decades, SIPI's parent company, Sinopharm has established a number collaborative relationships and pharmaceutical joint ventures with companies from the US, Japan, and Europe.

在过去的三十年中,SIPI的母公司,国药集团已与美国、日本和欧洲公司建立了一系列的合作关系和制药合资公司。

SIPI will pay Pharming €1.26 million upfront for the collaboration and a total of €0.84 million technology transfer related milestones associated with the implementation of the first technology transfer Ruconest (conestat alfa).

SIPI 将支付 Pharming 首付款 126 万欧元和 84 万欧元的第一批技术转让的里程碑式付款。

For every product developed by and manufactured, SIPI will pay Pharming a number of clinical and regulatory milestones. SIPI will supply Pharming on a cost plus basis for world- wide commercialisation. Pharming will pay SIPI 4% royalties on global sales (ex-China) and SIPI will pay Pharming 4% royalties on sales in China.

对于每一个 Pharming 产品开发,SIPI 将支付 Pharming 临床和监管的里程碑。 SIPI 将向 Pharming 提供全球商业化的成本加价基础。Pharming 将向 SIPI 支付全球销售(不包括中国)的 4%的特许权使用费,SIPI 将向 Pharming 支付在中国销售的 4%的特许权使用费。

Until the technology transfer is completed and a Chinese marketing authorisation for SIPI produced conestat alfa has been granted, Pharming will supply SIPI with Ruconest® as an import drug for China, at a cost plus basis and 4% royalties and SIPI will pay Pharming a €0.3 million milestone upon receipt of a Ruconest® import license for China.

直到完成技术转让和 SIPI 产生 conestat alfa 中国市场授权已被授予,Pharming 将向 SIPI 提供 Ruconest®作为中国进口药的支持,按成本加利润的基础和 4%的特许权使用费,当获得®Ruconest 的中国进口许可证时 SIPI 将向 Pharming 支付 30 万欧元的里程碑式付款。

Sijmen De Vries, Chief Executive of Pharming commented: Sijmen De Vries Pharming 集团 的首席执行官评论

"This collaborative product development with SIPI, aimed at developing new recombinant products in a cost effective manner, is a significant strategic achievement and will drive the future growth of Pharming. The combination of SIPI's vast resources and product development capabilities and Pharming's platform will allow us to jointly develop a biological pipeline by engaging in future multiple product development activities and significantly increase the output of our platform. This collaboration represents an important source of future products, including for the fastest growing pharmaceutical market in the world; China."

"此次与 SIPI 联合产品发展的初衷,旨在以成本效益的方式开发新的重组产品,是一个重大战略成果和将推动 Pharming 未来的增长。 SIPI 丰富的资源和产品研发能力与 Pharming 平台的结合,将使我们通过未来多个产品开发活动和我们平台产出的显著增长联合开发生物产品线。此次合作代表未来产品的重要来源,包括全球和中国的快速增长的医药市场。

Dr. Weigen Lu, President of SIPI commented:

SIPI 院长 陆伟根评论:

"Combining Pharming's validated technology platform with SIPI's capabilities in manufacturing, development, domestic regulatory and Sinopharm's commercialisation network, we have created an opportunity to provide for China's rapidly increasing need to domestically developed world- class quality biological medicines and to bringing to Chinese patients affordable biological medicines, and by supplying Pharming, we can become a global exporter of such domestically produced competitive world-class biological medicines."

About Pharming Group NV

Pharming Group NV is developing innovative products for the treatment of unmet medical needs. RUCONEST® (conestat alfa) is a recombinant human C1 esterase inhibitor approved for the treatment of angioedema attacks in patients with HAE in all 27 EU countries plus Norway, Iceland and Liechtenstein, and is distributed in the EU by Swedish Orphan Biovitrum. RUCONEST® is partnered with Santarus, Inc. (NASDAQ: SNTS) in North America and a Biologics License Application (BLA) for RUCONEST® is under review by the U.S. Food and Drug Administration. The product is also being evaluated for various follow-on indications. Pharming has a unique GMP compliant, validated platform for the production of recombinant human proteins that has proven capable of producing industrial volumes of high quality recombinant human protein in a more economical way compared to current cell based technologies. In July 2013, the Platform was partnered with Shanghai Institute for Pharmaceutical Industry (SIPI), a Sinopharm Company, for joint global development of new products. Pre- clinical development and manufacturing will take place at SIPI and are funded by SIPI. Pharming and SIPI initially plan to utilise this platform for the development of rhFVIII for the treatment of Haemophilia A. Additional information is available on the Pharming website, www.pharming.com.

About SIPI/ Sinopharm

Shanghai Institute for Pharmaceutical Industry (SIPI) was established in 1957 and became part of Sinopharm in 2010. Within Sinopharm, SIPI is an integrated applied science institute with a long history and strong capability in Chinese pharmaceutical industry, SIPI discovers, develops medicines and transfers technologies. In addition, SIPI has a graduate school of Pharmacy.

China National Pharmaceutical Group Corporation, (Sinopharm) is the largest medical and healthcare group in China which is directly managed by State-owned Assets Supervision and Administration Commission of the State Council (SASAC), with the core businesses of distribution, logistics, retail, scientific research and manufacture of healthcare related products. Associated built on the basis of the four state-owned companies: China National Pharmaceutical (Group) Corporation, China National Pharmaceutical Industry Corporation, China National Pharmaceutical Foreign Trade Corporation and China National Medical Equipment Industry Corporation, Sinopharm was established in 1998. In 2003, China National Group Corporation of Traditional & Herbal Medicine joined Sinopharm. In 2009, Sinopharm restructured with China National Bio-tech Group (CNBG). As well as in 2010, Shanghai Institute of Pharmaceutical Industry (SIPI) and China National Service Corporation for Chinese Personnel Working Abroad (CNSC) joined Sinopharm. So far, Sinopharm owns 10 wholly owned or holding subsidiaries, and 5 listed companies including Sinopharm Group Co., Ltd. (01099.HK), China National Medicines Co., Ltd. (600511.SH), Beijing Tiantan Biological Products Co., Ltd. (600161.SH), Shyndec Pharmaceutical Co., Ltd. (600420.SH) and Shenzhen Accord Pharmaceutical Co., Ltd. (200028.SZ). The sales revenue of Sinopharm exceeded RMB 160 billion in 2012. It is the only Chinese pharmaceutical company whose sales revenue exceeds RMB 100 billion.

Sinopharm is aiming to be an international pharmaceutical and healthcare group which covering the whole industrial chain and can give strong impetus to the industry as well as the first Chinese pharmaceutical company of the Global Top 500 Corporations during the period of "the 12th Five-Year-Plan".

About RUCONEST® and Hereditary Angioedema

RUCONEST (conestat alfa) is a recombinant version of the human protein C1 esterase inhibitor, and is produced with Pharming's proprietary transgenic technology. RUCONEST is approved in Europe for the treatment of acute angioedema attacks in patients with HAE, a genetic disorder in which the patient is deficient in or lacks a functional plasma protein C1 esterase inhibitor, resulting in unpredictable and debilitating episodes of intense swelling. The swelling may occur in one or more anatomical areas, including the extremities, face, trunk, genitals, abdomen and upper airway. The frequency and severity of HAE attacks vary and are most serious when they involve laryngeal edema, which can close the upper airway and cause death by asphyxiation. According to the U.S. Hereditary Angioedema Association, epidemiological estimates for HAE range from one in 10,000 to one in 50,000 individuals. RUCONEST is an investigational drug in the U.S. and has been granted orphan drug designation by the FDA both for the treatment of acute attacks of HAE and for prophylactic treatment of HAE.

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.

本新闻稿中包含的前瞻性陈述涉及已知和未知风险,不确定性和其他因素,可能导致本公司的业绩或成就有重大不同的实际结果,业绩或成果明示或暗示的前瞻性陈述。

About Factor VIII and Haemophilia A

Haemophilia A is an X chromosome linked hereditary disorder caused by defects in the Factor VIII (FVIII) gene that lead to lower levels of the functional FVIII protein. Lack of functional FVIII diminishes the body's clotting ability, which in turn can lead to damaging or fatal bleeding episodes. The global rhFVIII market was estimated to worth US\$3.8 billion in 2009, with 90% of sales in the developed markets and very high unmet medical needs in the developing markets, such as China. In addition, only approximately 50% of the world-wide estimated haemophilia market can currently be supplied with appropriate FVIII therapy. Hence, there is still a high unmet medical need in this field with an estimated total market potential of US\$10 billion.

A型血友病是一种 X 染色体相连因子 VIII(FVIII)基因缺陷引起的遗传性疾病,导致功能 FVIII 蛋白水平较低。缺乏功能性 FVIII 会减弱身体的凝血能力,进而可以导致损伤或致命的出血性抽血。全球 rhFVIII 市场预计 2009 年达到 38 亿美元,90%的销售是在发达国家市场和非常高的未满足的医药需求的如中国这样的发展中国家市场,。此外,目前在全球范围内血友病市场估计只有约50%的供给适当的 FVIII 治疗。因此,在此领域,仍然有很高的未满足的医药需求,预估大约有100 亿美元的市场潜力

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