Pharming receives EMA approval of new facility for expansion of RUCONEST® production

Highlights:

- New production facility will significantly increase production capacity of RUCONEST®
- Product manufactured at the new facility during the approval process is now available for distribution within the EU

Leiden, The Netherlands, 21 January 2020: Pharming Group N.V. (Euronext Amsterdam: PHARM) today announced it has received European Medicines Agency (EMA) approval of a Type II Variation for a new production facility for the Company's lead product, RUCONEST®.

With the addition of this new facility, Pharming will significantly increase the production capacity of RUCONEST® as it becomes fully operational over the coming year. Pharming is now also able to release the product that was manufactured at the facility during the approval process for commercialisation in the EU. As previously announced, Pharming had identified a potential risk of short-term pressure on the supply of RUCONEST® for the European market due to increasing demand for the product. With the approval of this new facility, the Company believes the risk to supply is now greatly reduced.

The new facility's post-approval supplement (PAS) for the distribution of RUCONEST® in the US is still under review by the Food and Drug Administration (FDA). Approval of the new facility for distribution in the US is expected in H1 2020.

Sijmen de Vries, Chief Executive of Pharming, said:
"As we continue to see increasing demand for RUCONEST® in the treatment of hereditary angioedema, we are pleased to announce the approval of our new facility, which will enable us to significantly increase production capacity for supply to patients in the EU. In addition, as a result of our recent re-acquisition of RUCONEST®'s European distribution rights from Sobi, this capacity expansion will allow us to reach an even greater number of EU patients."

About Pharming Group N.V.

Pharming is a specialty pharmaceutical company developing innovative products for the safe, effective treatment of rare diseases and unmet medical needs. Pharming's lead product, RUCONEST® (conestat alfa) is a recombinant human C1 esterase inhibitor approved for the treatment of acute Hereditary Angioedema ("HAE") attacks in patients in Europe, the US, Israel and South Korea. The product is available on a named-patient basis in other territories where it has not yet obtained marketing authorisation.

RUCONEST® is commercialised by Pharming in the USA and in Europe, and the Company holds all other commercialisation rights in other countries not specified below. In some of these other countries distribution is made in association with the HAEi Global Access Program (GAP). RUCONEST® is distributed in Argentina, Colombia, Costa Rica, the Dominican Republic, Panama, and Venezuela by Cytobioteck, in South Korea by HyupJin Corporation and in Israel by Kamada.

RUCONEST® is also being evaluated for various additional indications. Pharming's technology platform includes a unique, GMP-compliant, validated process for the production of pure recombinant human proteins that has proven capable of producing industrial quantities of high quality recombinant human proteins in a more economical and less immunogenetic way compared with current cell-line based methods.

In addition to RUCONEST® and variants of recombinant human C1 esterase inhibitor, Pharming has recently in-licensed leniolisib from Novartis, a small molecule which is in a registrational study for APDS, a form of Primary Immunodeficiency.

Leads for enzyme replacement therapy ("ERT") for Pompe and Fabry's diseases are also being produced and optimised respectively at present, with additional programs not involving ERT also being explored at an early stage.

Pharming has a long term partnership with the China State Institute of Pharmaceutical Industry ("CSIPI"), a Sinopharm company, for joint global development of new products, starting with recombinant human Factor VIII for the treatment of Haemophilia A. Preclinical development and manufacturing will take place to global standards at CSIPI and its affiliates and are funded by CSIPI. Clinical development will be shared between the partners with each partner taking the costs for their territories under the partnership.

Forward-looking Statements

This press release of Pharming Group N.V. and its subsidiaries ("Pharming", the "Company") may contain forward-looking statements including without limitation those regarding Pharming's financial projections, market expectations, developments, partnerships, plans, strategies and capital expenditures.

The Company cautions that such forward-looking statements may involve certain risks and uncertainties, and actual results may differ. Risks and uncertainties include without limitation the effect of competitive, political and economic factors, legal claims, the Company's ability to protect intellectual property, fluctuations in exchange and interest rates, changes in taxation laws or rates, changes in legislation or accountancy practices and the Company's ability to identify, develop and successfully commercialize new products, markets or technologies.

As a result, the Company's actual performance, position and financial results and statements may differ materially from the plans, goals and expectations set forth in such forward-looking statements. The Company assumes no obligation to update any forward-looking statements or information, which should be taken as of their respective dates of issue, unless required by laws or regulations.

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