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

Highlights:

- New production site for starting material will significantly increase production capacity of RUCONEST®
- Product manufactured with material from the new site during the approval process is now also immediately available for distribution within the USA.

Leiden, The Netherlands, 9 March 2020: Pharming Group N.V. (Euronext Amsterdam: PHARM) today announced it has also received US Food and Drug Administration (FDA) approval of Pharming's Prior Approval Supplement to add the new Netherlands production facility of starting material to the Biologics License Application (BLA) to support its lead product, RUCONEST®.

With the addition of this new facility for US supplies as well, Pharming can continue to expand sales in all markets in the coming year. Pharming is now also able to release the product that is manufactured with starting material from the facility for commercialisation in the USA. As previously announced, Pharming had already received approval for output from the new facility from the European Medicines Agency for commercial use in the European Union.

Sijmen de Vries, Chief Executive of Pharming, said:
"We are pleased to announce this approval by the FDA of our new facility, which will enable us to meet increasing demand for RUCONEST® in the treatment of hereditary angioedema for patients in the USA as well as for those in the EU. Following on from the EMA approval announced earlier this year in January, this gives us sufficient capacity for current demands as we continue to build for the future. "

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 US 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 production process that has proven capable of producing industrial quantities of pure high quality recombinant human proteins in a more economical and less immunogenic way compared with current cell-line based methods.

Leads for enzyme replacement therapy ("ERT") for Pompe and Fabry's diseases are also being produced and optimised respectively at present.

Pharming has recently in-licensed leniolisib from Novartis, a small molecule and selective PI3Kδ inhibitor, which is in a registrational study for activated PI3K-delta syndrome (APDS), a rare form of Primary Immunodeficiency.

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.

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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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