

Pharming signs agreement with NewBridge Pharmaceuticals for the commercialization of RUCONEST® in the Middle East and North Africa

Leiden, The Netherlands, 20 July 2021: Pharming Group N.V. (“Pharming” or “the Company”) (Euronext Amsterdam: PHARM/Nasdaq: PHAR) announces it has entered into an exclusive licence agreement with NewBridge Pharmaceuticals (“NewBridge”) for the distribution of RUCONEST® (conestat alfa) in the Middle East and North Africa (“MENA”).

NewBridge, headquartered in Dubai, United Arab Emirates, is a regional specialty company, with a comprehensive pharmaceutical platform of services and expertise, established to bridge the access gap and partner with global pharma and biotech companies to in-license and commercialize US Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved innovative therapeutics that address unmet medical needs into MENA.

Under the terms of the agreement, NewBridge will work closely with Pharming to provide access for RUCONEST® for the treatment of acute hereditary angioedema (“HAE”) in MENA. NewBridge will be responsible for the named patient supply and, where applicable, marketing of RUCONEST® in the region.

RUCONEST® is a plasma-free recombinant human C1 esterase inhibitor (“rhC1INH”) protein replacement therapy approved for the treatment of acute attacks of HAE in adults and children aged two years and over.¹ RUCONEST® is approved by the FDA and EMA and commercialised in over 20 countries.

HAE is a rare genetic condition characterized by recurrent, unpredictable episodic swellings of mucosal or cutaneous sites, causing pain, disfigurement, and disability which last for hours, and occasionally, several days.² For patients, the disorder is disabling and can be fatal if not treated.²

Sijmen de Vries, Chief Executive Officer, Pharming Group commented:

“Pharming is committed to supporting patients with HAE, along with their caregivers, as they live with this debilitating disease. We are therefore delighted to enter into this agreement with NewBridge to ensure access to RUCONEST® in new geographies. NewBridge’s extensive experience in the Middle East and North Africa, along with their strategic focus in rare diseases, make them an ideal partner for Pharming in the region. We look forward to continuing to expand the global reach of RUCONEST®, in line with our growth strategy, to serve HAE patients with unmet medical needs.”

About RUCONEST®

RUCONEST® (recombinant C1 esterase inhibitor) is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).

RUCONEST® contains C1 esterase inhibitor at 50 U/kg. When administered at the onset of HAE attack symptoms at the recommended dose, RUCONEST® may help to return a patient’s C1 esterase inhibitor levels to normal range and relieve the symptoms of an HAE attack with a low recurrence of symptoms within 24 hours.

The most common side effect of RUCONEST® (seen in between 1 and 10 patients in 100) is nausea. For the full list of all side effects reported with RUCONEST®, see the package leaflet. RUCONEST® must not be used in patients with known or suspected allergy to rabbits. For the full list of restrictions, see the package leaflet.



RUCONEST® is the only recombinant C1 esterase inhibitor worldwide. RUCONEST® is approved by the US Food and Drug Administration (FDA) for the treatment of acute attacks in adult and adolescent patients with HAE since July 2014.

About NewBridge Pharmaceuticals

NewBridge Pharmaceuticals FZ LLC (NBP) is a privately owned company, established and headquartered in Dubai, United Arab Emirates since 2010 with an extended physical reach across the Middle East and North African countries (MENA).

NBP is a regional specialty pharmaceutical organization with a comprehensive platform of services and in-depth local expertise, focusing on licensing and commercializing USFDA & EMA approved innovative therapeutics that address unmet medical needs in the MENA Region, and offering a one-stop solution to access multiple geographies to companies wanting to expand their presence in the MENA region.

About Pharming Group N.V.

Pharming Group N.V. is a global, commercial stage biopharmaceutical company developing innovative protein replacement therapies and precision medicines for the treatment of rare diseases and unmet medical needs.

The flagship of our portfolio is our recombinant human C1 esterase inhibitor (rhC1INH) franchise. C1INH is a naturally occurring protein that down regulates the complement and contact cascades in order to control inflammation in affected tissues.

Our lead product, RUCONEST®, is the first and only plasma-free rhC1INH protein replacement therapy. It is approved for the treatment of acute hereditary angioedema (HAE) attacks. We are commercializing RUCONEST® in the United States, the European Union and the United Kingdom through our own sales and marketing organization, and the rest of the world through our distribution network.

In addition, we are investigating the clinical efficacy of rhC1INH in the treatment of further indications, including pre-eclampsia, acute kidney injury, and severe pneumonia as a result of COVID-19 infections.

Furthermore, we are leveraging our transgenic manufacturing technology to develop next-generation protein replacement therapies, most notably for Pompe disease, which is currently in preclinical development.

Forward-looking Statements

This press release contains forward-looking statements, including with respect to timing and progress of Pharming's preclinical studies and clinical trials of its product candidates, Pharming's clinical and commercial prospects, Pharming's ability to overcome the challenges posed by the COVID-19 pandemic to the conduct of its business, and Pharming's expectations regarding its projected working capital requirements and cash resources, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Pharming's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in Pharming's 2020 Annual Report and the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission, the events and circumstances discussed in such forward-looking statements may not occur, and Pharming's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Pharming as of the date of this release.

Inside Information

This press release relates to the disclosure of information that qualifies, or may have qualified, as inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation.

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2. Longhurst H, et al. Lancet 2012;379(9814):474-481.