FOR IMMEDIATE RELEASE

FDA Grants RUCONEST® (C1 Esterase Inhibitor [Recombinant]) Twelve-Year Reference Product Exclusivity

Leiden (Netherlands) and Bridgewater, N.J., Oct. 8, 2015 – Pharming Group NV (EURONEXT: PHARM) and Salix Pharmaceuticals announced today that the U.S. Food and Drug Administration (FDA) has granted 12 years of exclusivity to RUCONEST® (C1 esterase inhibitor [recombinant]) 50 IU/kg. The determination of exclusivity ensures that FDA will not approve before July 16, 2026 any applications for biosimilars of RUCONEST— i.e. applications for recombinant C1 esterase inhibitors referencing RUCONEST submitted under section 351(k) of the Public Health Service Act under the framework established by the Biologics Price Competition and Innovation Act of 2009.

RUCONEST was approved by the FDA on July 16, 2014, for the treatment of acute angioedema attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness was not established in HAE patients with laryngeal attacks.

A rare condition occurring in about 1 in 10,000 to 1 in 50,000 people worldwide, HAE is potentially life-threatening and stems from a genetic defect that impacts the production of C1-INH protein.[1] This can lead to a biochemical imbalance that causes swelling in various parts of the body, including the hands, feet and face.[1] Swelling in the intestinal wall can also cause severe abdominal pain, nausea and vomiting.[1] Due to its rarity, many patients often remain undiagnosed for years.[1]

RUCONEST is contraindicated in patients with a history of allergy to rabbits, or rabbit-derived products, and patients with a history of life-threatening immediate hypersensitivity reactions to C1 esterase preparations, including anaphylaxis.

Under the Biologics Price Competition and Innovation Act of 2009, exclusivity for licensed biologics—like RUCONEST—can be granted for a 12-year period from the date of first licensure of the product.

“We are pleased the anticipated exclusivity for RUCONEST has been formally granted,” said Deb Jorn, Executive Vice President/Company Group Chairman, Valeant Pharmaceuticals. “The response to RUCONEST has been positive since its launch in November 2014 and we look forward to continued growth.”

Sijmen de Vries, Pharming’s CEO, commented: “Pharming strived to make RUCONEST available to the HAE patient community in the US, because we were aware of the great value and benefits that RUCONEST could provide to patients. That the FDA granted 12 year exclusivity for RUCONEST reinforces this long-standing commitment and we are excited to continue to work closely with Salix to ensure patients in the US have access to RUCONEST.”

PHARMING

Please see Important Safety Information below and click here for Prescribing Information. For more information on RUCONEST visit www.RUCONEST.com

INDICATION:

RUCONEST® (C1 esterase inhibitor [recombinant]) is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness in clinical studies was not established in HAE patients with laryngeal attacks.

Important Safety Information for RUCONEST

RUCONEST® (C1 esterase inhibitor [recombinant]) is not for everyone. Do not take RUCONEST if you have a known history of allergy to rabbits or products from rabbits. Do not take RUCONEST if you have a history of life-threatening immediate allergic reactions to C1 esterase inhibitor preparations, including anaphylaxis.

If you experience hives, pale red, raised, itchy bumps (urticaria), tightness of the chest, wheezing, low blood pressure (hypotension), and/or anaphylaxis during or after injection of RUCONEST, discontinue RUCONEST and immediately contact your doctor. These may be signs and symptoms of allergic reactions.

Products similar to RUCONEST have been associated with thromboembolic events. Before taking RUCONEST, please notify your doctor if you have an indwelling venous catheter/access device, history of blood clot (thrombosis), been told you have thickening of the walls of your arteries (atherosclerosis), use oral contraceptives (i.e. estrogen or progesterone), are extremely overweight and have significant difficulty moving around.

If you are pregnant, planning to become pregnant, or nursing, talk to your healthcare provider before taking RUCONEST.

The most common RUCONEST side effects in clinical studies include: headache, nausea, and diarrhea. Serious side effect anaphylaxis has been reported in RUCONEST clinical studies.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch/, or call 1-800-FDA-1088.

For product information, adverse event reports, and product complaint reports, please contact:

Salix Product Information Call Center
Phone: 1-800-508-0024
Fax: 1-510-595-8183
Email: Salix@medcomsol.com

Please click here for Prescribing Information for RUCONEST.

About RUCONEST®

RUCONEST® (C1 esterase inhibitor [recombinant]) is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness in clinical studies was not established in HAE patients with laryngeal attacks.

HAE is caused by a deficiency of the C1 esterase inhibitor protein, which is present in blood and helps control inflammation (swelling) and parts of the immune system. A shortage of C1 esterase inhibitor can lead to repeated attacks of swelling, pain in the abdomen, difficulty breathing and other symptoms. RUCONEST® contains C1 esterase inhibitor at 50 IU/kg.

When administered at the onset of HAE attack symptoms at the recommended dose, RUCONEST may help to return a patient's C1-INH levels to normal range and relieve the symptoms of an HAE attack with a low recurrence of symptoms within 24 hours.

RUCONEST is the only recombinant C1-INH approval from the U.S. Food and Drug Administration (FDA) and was approved in July 2014.

RUCONEST is designated as an orphan drug by the FDA for the treatment of acute attacks of angioedema caused by hereditary or acquired C1-INH deficiency.

About Salix Pharmaceuticals

Salix Pharmaceuticals, a division of Valeant Pharmaceuticals International, Inc., develops and markets prescription pharmaceutical products and medical devices for the prevention and treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic products, complete any required development and regulatory submission of these products, and commercialize them through the Company's specialty sales forces.

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 the USA, Israel, all 28 EU countries plus Norway, Iceland, and Liechtenstein.

RUCONEST is commercialized by Pharming in Austria, Germany and The Netherlands.

RUCONEST is distributed by Swedish Orphan Biovitrum AB (publ) (SS: SOBI) in the other EU countries, and in Azerbaijan, Belarus, Georgia, Iceland, Kazakhstan, Liechtenstein,

Norway, Russia, Serbia, and Ukraine.

RUCONEST is partnered with Salix Pharmaceuticals, Ltd. ("Salix") in North America. Valeant Pharmaceuticals International, Inc. (NYSE: VRX/TSX: VRX) completed its acquisition of Salix Pharmaceuticals, Ltd. on April 1, 2015.

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. Leads for Enzyme Replacement Therapy (ERT) in Pompe, Fabry's and Gaucher's diseases are under early evaluation. The platform is partnered with Shanghai Institute of 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 recombinant human Factor VIII for the treatment of Haemophilia A.

For more information, please visit http://www.pharming.com

Pharming Disclosure Notice

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.

Pharming Group
Sijmen de Vries, Chief Executive Officer Tel: +31 71 5247400

FTI Consulting (Pharming media relations) Tel: +44 203 727 1136
Julia Phillips / Victoria Foster Mitchell

Salix Media Contact:
Sarah Hamilton
Edelman Public Relations on behalf of Salix Pharmaceuticals
Tel: +1 (404) 460-9675 or Sarah.Hamilton@edelman.com

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[1] US Hereditary Angioedema Association. What is HAE? http://www.haea.org/patients/what-is-hae. Accessed 7/6/2015.