

HAEi Global Access Program for RUCONEST® Now Live

Unique patient organization-driven program is enabling people with HAE who cannot access effective treatments to receive medication for the first time

Leiden, Netherlands and Burton-on-Trent, UK – 21 July 2015 – Pharming Group N.V. (“Pharming or the Company”), Euronext: PHARM) and Clinigen Group plc (‘Clinigen’ or the ‘Group’, AIM: CLIN) today announce that their global collaboration to provide access to Pharming’s RUCONEST® (conestat alfa) is now live. The unique access program was initiated by HAEi, the International Patient Organization for C1- Inhibitor Deficiencies.

RUCONEST is a recombinant human C1- inhibitor, approved by the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) for the treatment of acute attacks of hereditary angioedema (HAE). The “HAEi GAP” program enables patients in all countries where RUCONEST is not commercially available to gain access to the drug through an ethical and regulatory compliant “Named Patient Program” mechanism.

Physicians wishing to request RUCONEST through the HAEi GAP program should contact the Clinigen customer services team at customer.services@clinigengroup.com / +44 1283 494340.

“HAEi is committed to securing access to HAE medications for patients across the globe,” said Anthony J. Castaldo, President of HAEi. “We are extremely proud to have established HAEi GAP with our current partners and to be able to announce that, from today, physicians are able to request RUCONEST to meet the needs of their patients.”

Sijmen de Vries, CEO, Pharming said: “As the first pharmaceutical company to partner with HAEi and provide access to RUCONEST through HAEi GAP, we are leading the charge to improve the lives of those HAE patients that otherwise would continue suffering from this debilitating and unpredictable disease.”

Simon Estcourt, Managing Director, Managed Access, Clinigen Group said: “We are very pleased to work with Pharming to help HAEi realize their mission to ensure that sufferers of hereditary angioedema worldwide can access this effective and potentially life-saving treatment. The ground-breaking program provides RUCONEST to patients in an ethical and compliant way, removing the need and the risk for patients to resort to other less reliable or even illegal sources of the drug.”

– Ends –

About HAE

Hereditary Angioedema (HAE) is a rare genetic disorder. It is characterized by spontaneous and recurrent episodes of swelling (edema attacks) of the skin in different parts of the body, as well as in the airways and internal organs. Edema of the skin usually affects the extremities, the face, and the genitals. Patients suffering from this kind of edema often withdraw from their social lives because of the disfiguration, discomfort and pain these symptoms may cause. Almost all HAE patients suffer from bouts of severe abdominal pain, nausea, vomiting and diarrhea caused by swelling of the intestinal wall.

Edema of the throat, nose or tongue is particularly dangerous and potentially life-threatening and can lead to obstruction of the airway passages. Although there is currently no known cure for HAE, it is possible to treat the symptoms associated with edema attacks. HAE affects about 1 in 10,000 to 1 in 50,000 people worldwide. Experts believe that a lot of patients are still seeking the right diagnosis: although HAE is (in principle) easy to diagnose, it is frequently identified very late or not discovered at all. The reason HAE is often misdiagnosed is

because the symptoms are similar to those of many other common conditions such as allergies or appendicitis. By the time it is diagnosed correctly, the patient has often been through a long lasting ordeal.

About RUCONEST®

RUCONEST® (C1 Esterase Inhibitor [Recombinant]) 50 IU/kg is an injectable medicine that is used to treat acute angioedema attacks in adult and adolescent patients with hereditary angioedema (HAE). 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 works to return a patient's C1-INH levels to normal range and quickly begins to relieve the symptoms of an HAE attack with a low recurrence of symptoms. RUCONEST is the first and only plasma-free, recombinant C1-INH approval from the U.S. Food and Drug Administration (FDA) and was approved in July 2014 and by the European Medicines Agency (EMA) in October 2010.

About Global Access Programs

Global Access Programs provide biopharmaceutical companies with a way to allow ethical access to their pre-license/unlicensed medicines to help patients with unmet medical needs. Access is provided in response to physician requests, in a fully compliant manner, where no alternative treatment options are available.

About HAEi

HAEi – International Patient Organization for C1 inhibitor Deficiencies - is a global organization dedicated to raising awareness of C1 inhibitor deficiencies around the world. It is a non-profit international network of national HAE patient Associations. HAEi is established to promote co-operation, co-ordination and information sharing between HAE Specialists and National HAE Patient Associations in order to help facilitate the availability of effective diagnosis and management of C1 inhibitor deficiencies throughout the world. Our purpose is to join the efforts and experience of the global HAE community to achieve optimal standards of care and treatment for all those patients affected by C1 inhibitor deficiencies.

For more information, please visit: www.haei.org

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 commercialised 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. Salix is part of Valeant Pharmaceuticals International, Inc. (NYSE: VRX/TSX: VRX)

RUCONEST is also being investigated in a randomised Phase II clinical trial for prophylaxis of HAE, in a Phase II clinical trial for the treatment of HAE in young children (2-13 years of age) and evaluated for various additional 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. 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>

About Clinigen Group

Clinigen Group is a global pharmaceutical and services company with a unique business model dedicated to delivering the right drug to the right patient at the right time. The Group consists of four complementary businesses that provide medicines to patients with unmet need through clinical trials, licensed and unlicensed supply; Clinigen Specialty Pharmaceuticals (SP), Clinigen Clinical Trial Services (CTS), Idis Managed Access (MA) and Idis Global Access (GA).

We are global leaders in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and doctors for patients with a high unmet need. Our Managed Access business provides early access to unlicensed investigational medicines on behalf of pharmaceutical companies.

For more information, please visit www.clinigengroup.com

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