

8th October 2021

CLINIGEN

Clinigen signs agreement with Humanigen for Lenzilumab Managed Access Program

Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical Services and Products company, announces it has signed an exclusive agreement with Humanigen, Inc. ('Humanigen') to implement a Managed Access Program for lenzilumab.

Once set up the program will enable access to lenzilumab on a case-by-case basis for hospitalized patients with COVID-19 where the treating physician deems there to be no suitable alternatives and where regulations allow. The program will be available in the following 16 European countries: Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, France, Greece, Ireland, Lithuania, Luxembourg, Netherlands, Portugal, Spain, Sweden, and Switzerland. Lenzilumab is an investigational product and is not currently authorized or approved in any country.

Under the terms of the agreement, Clinigen will manage key elements of the program including regulatory oversight, logistics and access management.

Pete Belden, Executive Vice President Services Division, Clinigen, said:

"We are pleased to partner with Humanigen to offer this important treatment option to help address a significant unmet need for hospitalized patients across Europe. This agreement underlines Clinigen's strength in partnering with biotechnology companies to provide services that enable quicker and broader access to critical medicines."

Timothy E. Morris Chief Operating Officer and Chief Financial Officer, Humanigen, said:

"While we complete a Marketing Authorization Application for lenzilumab and await the associated review by the European Medicines Agency, as well as a decision regarding conditional marketing authorization, the Managed Access Program will enable Humanigen to respond positively to requests for access from healthcare professionals to treat hospitalized patients where allowed by the local competent authorities. We look forward to working with Clinigen."

Patients seeking information should contact their physician.

– Ends –

Contact details

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Notes to Editors

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global, specialist pharmaceutical services and products company focused on providing ethical access to medicines. Its' mission is to deliver the right medicine to the right patient at the right time. The Group operates from sites in North America, Europe, Africa and the Asia Pacific.

Clinigen has more than 1,000 employees across five continents in 14 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 34 of the top 50 pharmaceutical companies; interacting with over 20,000 healthcare professionals across more than 120 countries.

For more information on Clinigen, please visit <http://www.clinigen.com>

About Humanigen

Humanigen is a clinical-stage biopharmaceutical company focused on preventing and treating an immune hyper-response called 'cytokine storm'. Humanigen has submitted lenzilumab to Medicines and Health Regulatory Agency in the United Kingdom for a rolling review towards potential Marketing Authorization. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with COVID-19 and CD19-targeted CAR-T cell therapies and is also exploring the effectiveness of lenzilumab in other inflammatory conditions such as acute Graft versus Host Disease in patients undergoing allogeneic hematopoietic stem cell transplantation, eosinophilic asthma, and rheumatoid arthritis. For more information, visit www.humanigen.com and follow Humanigen on LinkedIn, Twitter, and Facebook.