

Press release
Fontenay-Sous-Bois, 9 February 2022

Cenexi and Humanigen announce a partnership to produce lenzilumab, one of the most promising treatments for severe forms of Covid-19, in France

- Cenexi will shortly become the exclusive producer of lenzilumab, one of the ten most promising treatments against severe forms of Covid-19, in France for the next five years.
- The batches will be manufactured in its state-of-the-art factory in Hérouville-Saint-Clair (Calvados).
- Cenexi also intends to offer Humanigen broader services to consolidate an end-to-end supply chain for lenzilumab on the European market.

Cenexi, a major French CDMO specializing in the formulation, development, and manufacture of innovative sterile products, and Humanigen, an American biopharmaceutical company, have announced a partnership to make Cenexi the exclusive supplier of lenzilumab in Europe for the next five years. Under the agreement, Humanigen will transfer its technology and expertise to Cenexi to allow it to produce lenzilumab batches on a latest-generation line on its Hérouville-Saint-Clair (Calvados) site, specializing in the manufacture and filling of sterile liquid vials.

Beyond its industrial-scale manufacturing and packaging capabilities, Cenexi will also be offering broader services to Humanigen: upstream of manufacturing, during drug development stages, and downstream, by providing regulatory or logistical services on the French and European markets.

“Our partnership with Cenexi is intended to establish a sustainable production and supply chain for lenzilumab in Europe”, commented Cameron Durrant, CEO of Humanigen. Cenexi is an ideal partner for sterile filling. Due to its custom service offer, its agility, its flexibility, and the responsiveness of its teams, we plan to extend our partnership beyond a basic customer-supplier relationship. In the longer term, we want Cenexi to become the cornerstone of the entire lenzilumab supply chain in France and Europe”, he assured.

Humanigen has submitted day before yesterday an early access request for lenzilumab to the French National Authority for Health (HAS), in order to allow patients in a therapeutic impasse to receive, on an exceptional and temporary basis, the treatment.

“This partnership strengthens our position as the privileged CDMO of innovative biotechs, consisting in providing patients with the most innovative therapies. Our objective is to establish a sustainable supply chain for these therapies, in order to consolidate a strong and agile healthcare industry in France.” stated Christophe Durand, CEO of Cenexi. We are a major CDMO stakeholder, specializing in the sterile production of complex drugs. Our partnership with Humanigen demonstrates the quality of our facilities, the industrial capacities available thanks to the investments made, and the expertise of our teams. Discussions are also underway with Humanigen to manage the entire supply chain for lenzilumab in France and Europe”, he continued.

Lenzilumab, one of the ten most promising treatments for Covid-19 listed by the EMA

Lenzilumab is a monoclonal antibody that neutralizes excess production of GM-CSF, an inflammatory factor that stimulates granulocyte and macrophage colonies and triggers the cytokine storm, a disproportionate immune reaction observed in severe forms of SARS-CoV-2 infection. It binds itself to and neutralizes GM-CSF, improving outcomes for hospitalized hypoxic patients. Lenzilumab is currently being registered on the French market with the ANSM, via an Early Access Authorization (EAA) procedure, as well as on the European market, via a centralized registration procedure with the EMA (European Medicines Agency).

About Cenexi

Cenexi, a major French CDMO operating in Europe with 1,500 employees and some €200 million in turnover (2021), is experiencing steady growth with four production sites (Fontenay-sous-Bois, Osny, and Hérouville-Saint-Clair in France and Braine-l'Alleud in Belgium) and a center of expertise dedicated to new product introduction.

Created in 2004, the Cenexi Group is positioned on the very dynamic international market for drugs with major therapeutic indications, drawing on its spirit of innovation and its extensive expertise in the manufacture and development of products.

The Group's new management team has revitalized the company, in particular, by strengthening its sterile expertise which already represents 70% of its business.

Cenexi has the facilities to produce many pharmaceutical forms and has strong expertise in cytotoxic, hormonal, and narcotic drugs.

About Humanigen

Humanigen, Inc. (Nasdaq: HGEN) (“Humanigen”), is a clinical stage biopharmaceutical company specializing in the prevention and treatment of an overactive immune response called *cytokine shock syndrome*.

Lenzilumab is a first-in-class antibody that binds itself to and neutralizes the granulocyte-macrophage colony-stimulating factor (GM-CSF). Results from preclinical models indicate that GM-CSF is an upstream regulator of various inflammatory cytokines and chemokines involved in cytokine shock.

In addition to developing Lenzilumab as a treatment for cytokine shock associated with COVID-19, Humanigen is exploring the effectiveness of Lenzilumab in other inflammatory conditions, such as acute graft-versus-host disease in patients undergoing allogeneic hematopoietic stem cell transplantation with eosinophilic asthma and rheumatoid arthritis.

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