



NEWS RELEASE

# Humanigen's Partner in South Korea Receives Ministry of Food and Drug Safety (MFDS) Approval to Conduct Phase 1 Study of Lenzilumab

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BURLINGAME, Calif.--(BUSINESS WIRE)-- Humanigen, Inc. (Nasdaq: HGEN) ("Humanigen"), today announced its development and commercialization partners for South Korea and the Philippines, Telcon RF Pharmaceutical, Inc. ("Telcon") and KPM Tech Co., Ltd. ("KPM Tech"), have received approval from South Korea's MFDS (the South Korean equivalent of the U.S. FDA) to conduct a Phase 1 clinical study of lenzilumab, which may support potential use in the treatment of hospitalized COVID-19 patients.

The study, to be conducted by Telcon and KPM Tech at the Seoul National University Hospital, is a randomized, placebo-controlled, double-blind, single-dose, dose escalation of lenzilumab in 20 healthy Korean adults. The primary endpoints of the study are the safety, tolerability, and pharmacokinetics of lenzilumab. If FDA grants emergency use authorization for lenzilumab in the treatment of hospitalized COVID-19 patients in the United States, Telcon and KPM Tech plan to apply to MFDS for conditional approval for importation of lenzilumab for use in Korea. Support for conditional approval would be based on data from this phase 1 study and the existing data from Humanigen's Phase 3 LIVE-AIR study. Additional clinical trials are not expected to be necessary in this situation.

"We are excited to see our partners Telcon and KPM Tech advance their efforts to develop lenzilumab for potential use in South Korea," said Dr. Cameron Durrant, CEO of Humanigen. "We believe the data for lenzilumab from our Phase 3 LIVE-AIR study demonstrates the meaningful improvement in patient care that is possible with the use of lenzilumab to treat patients hospitalized with COVID-19 pneumonia. We are hopeful that these data, alongside data generated in Korea by our partners, will allow for the use of lenzilumab in South Korea."

Like many countries, South Korea is experiencing rising number of COVID-19 cases, particularly due to the spread of the Delta variant. Although 32% of the population has received at least one vaccine dose, the Delta variant is complicating efforts to control the spread and contributing to new records for daily infections.<sup>1</sup> Treatments for hospitalized COVID-19 patients remains an urgent medical need to prevent the potential progression of symptoms and intensive care.

## About Humanigen, Inc.

Humanigen, Inc. (Nasdaq: HGEN) (“Humanigen”), a clinical-stage biopharmaceutical company focused on preventing and treating an immune hyper-response called ‘cytokine storm’. Lenzilumab is a first-in class antibody that binds to and neutralizes granulocyte-macrophage colony-stimulating factor (GM-CSF). Results of preclinical models indicate GM-CSF is an upstream regulator of many inflammatory cytokines and chemokines involved in the cytokine storm. Early in the COVID-19 pandemic, investigation showed high levels of GM-CSF secreting T cells were associated with disease severity and intensive care unit admission. Humanigen’s Phase 3 LIVE-AIR study suggests early intervention with lenzilumab may prevent consequences of a full-blown cytokine storm in hospitalized patients with COVID-19. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with CD19-targeted CAR-T cell therapies and exploring the effectiveness of lenzilumab in other inflammatory conditions such as acute Graft versus Host Disease (GvHD) in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT), eosinophilic asthma, and rheumatoid arthritis. Humanigen is also developing a portfolio of clinical and pre-clinical therapies for the treatment of inflammation and immuno-oncology. For more information, visit [www.humanigen.com](http://www.humanigen.com) and follow Humanigen on LinkedIn, Twitter, and Facebook.

## About KPM Tech Co., Ltd/Telcon RF Pharmaceutical, Inc.

KPM Tech was established in March 1971 to develop and manufacture plating chemicals, fully automatic plating equipment products, and associated technologies. On January 7, 2003, KPM Tech was approved for registration and transaction on the KOSDAQ stock market of the Korea Exchange. Key areas of focus include the manufacture and sale of PCBs, electronic communication semiconductors, surface treatment chemicals for automobile parts, and fully automatic plating equipment. KPM Tech with its largest shareholder, Telcon RF Pharma, have also invested on new drug development companies such as Emmaus Life Sciences, Vivozon and Abion.

Telcon was established in January 1999 to produce connectors, cable assemblies, etc. used in the manufacture of wireless communication equipment and today also manufactures and commercializes pharmaceutical products. The company was listed on the KOSDAQ market on November 24, 2014 and major business sectors include Telcon RF and pharmaceuticals/biotechnology. The pharmaceutical/biotechnology business division operates a Korea Good Manufacturing Practice (KGMP) production facility to produce liquid formulation products and other formulations such as tablets, pills, and capsules. There is also a continued investment in the development of new drugs.

## Humanigen Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment, and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct,

and you should be aware that actual events or results may differ materially from those contained in the forward-looking statements. Words such as "will," "expect," "intend," "plan," "potential," "possible," "goals," "accelerate," "continue," and similar expressions identify forward-looking statements, including, without limitation, statements regarding the ability of KPM Tech and Telcon to attain required regulatory approvals in the covered territories; the possibility of receipt of emergency use authorization from FDA for lenzilumab in hospitalized COVID-19 patients; and our other plans to explore the effectiveness of lenzilumab and other candidates in our development portfolio as therapies for other inflammation and immune-oncology indications.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in our lack of profitability and need for additional capital to grow our business; our dependence on partners to further the development of our product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory authorizations and approvals and launch of any new pharmaceutical product; the outcome of pending or future litigation; and the various risks and uncertainties described in the "Risk Factors" sections of our latest annual and quarterly reports and other filings with the SEC.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not rely upon any forward-looking statements as predictions of future events. We undertake no obligation to revise or update any forward-looking statements made in this presentation to reflect events or circumstances after the date hereof, to reflect new information or the occurrence of unanticipated events, to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, in each case, except as required by law.

1. Cha, S. (2021, July 20). South Korea reports record daily infections as Delta variant drives surge. Reuters. <https://www.reuters.com/world/asia-pacific/south-korea-reports-new-daily-record-1784-covid-19-cases-kdca-2021-07-21/>

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