

Humanigen Announces COVID-19 Case Report Demonstrating Rapid Resolution and Discharge after Single IND Emergency Use Authorization of Lenzilumab™

- Case report demonstrated rapid resolution of hypoxemia and mobility and potential benefit of lenzilumab beyond the initial acute hyper-inflammatory window
- After 13 weeks of hospitalization, administration of lenzilumab resulted in rapid improvement in oxygenation and subsequent discharge

Burlingame, CA, October 2, 2020 – [Humanigen, Inc.](#), (Nasdaq: HGEN) (“Humanigen”), a clinical stage biopharmaceutical company focused on preventing and treating an immune hyper-response called ‘cytokine storm,’ today announced that a patient case report on the use of lenzilumab™ in critical COVID-19 was published online at OSF Preprints. The case report, titled “COVID-19 associated chronic ARDS successfully treated with lenzilumab” is available at: <https://osf.io/xusr9/>.

The published case describes a 77-year-old Caucasian male patient with a past medical history of type II diabetes, coronary artery disease with coronary artery bypass graft, systolic heart failure, severe chronic obstructive pulmonary disease (COPD) with emphysema and obstructive sleep apnea. The patient tested positive for SARS-CoV-2 and was admitted to the ICU in March 2020 for COVID-19 and put on respiratory isolation. The patient was treated with steroids, broad spectrum antibiotics for community acquired pneumonia and bronchodilators for possible COPD exacerbation and hydroxychloroquine with zinc. The patient continued to deteriorate for the next 12 weeks with an increase in oxygen demand from continuous low-flow oxygen to high-flow and eventually intermittent bilevel positive airway pressure (BIPAP) and developed acute respiratory distress syndrome (ARDS) during that time.

At week 13 of hospitalization and multiple unsuccessful attempts at oxygen weaning, an emergency single use IND for lenzilumab, Humanigen’s Humaneered® anti-human granulocyte macrophage-colony stimulating factor (GM-CSF) monoclonal antibody drug candidate, was approved by the FDA and administered to the patient. Seven days following the administration of lenzilumab, the patient’s oxygen decreased from high-flow to low-flow nasal cannula and the patient was able to walk outside of his hospital room with physical therapy. Sixteen days post-treatment with lenzilumab, the patient was discharged from the hospital on home oxygen.

A separate case-control [study](#) of lenzilumab in severe and critical COVID-19 published in Mayo Clinic Proceedings demonstrated an 80% reduction in relative risk of invasive mechanical ventilation (IMV) and/or death for patients treated with lenzilumab compared to the matched control group. Lenzilumab is being evaluated in an ongoing Phase 3 trial and trial site locations can be found here: <https://www.humanigen.com/covid-19-sites>.

“The recent case-control study published by the Mayo Clinic suggests lenzilumab may improve clinical outcomes, oxygenation requirements, and improve lymphocyte counts in patients with severe and critical COVID-19 during the acute hyperinflammatory immune response,” said Juan Pulido, MD, Pulmonologist, Baptist Health Research Institute. “This patient case report suggests that lenzilumab may be beneficial to patients who are unable to wean off of supplemental oxygen and even those who have failed multiple rounds of prior therapy and are outside the initial acute hyper-inflammatory window.”

“This patient case underscores our urgency to continue our development program for lenzilumab in an effort to deliver a therapeutic that may potentially improve outcomes for hospitalized COVID-19 patients,” said Cameron Durrant, MD, MBA, chief executive officer of Humanigen. More details on Humanigen’s programs in COVID-19 can be found on the company’s website at www.humanigen.com under the [COVID-19 tab](#), and details of the US Phase 3 potential registration study can be found at clinicaltrials.gov using Identifier NCT04351152.

About Humanigen, Inc.

Humanigen, Inc. is developing its portfolio of clinical and pre-clinical therapies for the treatment of cancers and infectious diseases via its novel, cutting-edge GM-CSF neutralization and gene-knockout platforms. We believe that our GM-CSF neutralization and gene-editing platform technologies have the potential to reduce the inflammatory cascade associated with coronavirus infection. The company’s immediate focus is to prevent or minimize the cytokine release syndrome that precedes severe lung dysfunction and ARDS in serious cases of SARS-CoV-2 infection. The company is also focused on creating next-generation combinatory gene-edited CAR-T therapies using strategies to improve efficacy while employing GM-CSF gene knockout technologies to control toxicity. In addition, the company is developing its own portfolio of proprietary first-in-class EphA3-CAR-T for various solid cancers and EMR1-CAR-T for various eosinophilic disorders. The company is also exploring the effectiveness of its GM-CSF neutralization technologies (either through the use of lenzilumab™ as a neutralizing antibody or through GM-CSF gene knockout) in combination with other CAR-T, bispecific or natural killer (NK) T cell engaging immunotherapy treatments to break the efficacy/toxicity linkage, including to prevent and/or treat graft-versus-host disease (GvHD) in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT). Additionally, Humanigen and Kite, a Gilead Company, are evaluating lenzilumab in combination with Yescarta® (axicabtagene ciloleucel) in patients with relapsed or refractory large B-cell lymphoma in a clinical collaboration. For more information, visit www.humanigen.com.

Forward-Looking Statements

This release contains 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 our expectations for the Phase 3 study and the potential future development of lenzilumab, our pathway to our intended submission for, and potential receipt of, an Emergency Use Authorization and potential subsequent BLA from FDA, and statements regarding the potential for lenzilumab to be used to prevent or treat GvHD and, as sequenced therapy with Kite's Yescarta, in CAR-T therapies. 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; our dependence on partners to further the development of our product candidates; the costs and the uncertainties inherent in the development 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 and elsewhere in the Company's periodic and other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not place undue reliance on any forward-looking statements, which speak only as of the date of this release. We undertake no obligation to revise or update any forward-looking statements made in this press release to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

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