Mayo Clinic Study of Humanigen's Lenzilumab Shows Rapid Recovery and Discharge in Severe and Critical COVID-19 Patients

- **Median time to recovery and discharge of five days**
- **All patients were at high risk of progression, including four patients who were in the ICU prior to receiving lenzilumab**
- **No treatment emergent adverse events were attributable to lenzilumab**

Burlingame, CA, June 15, 2020 – Humanigen, Inc., **(HGEN)** ("Humanigen"), a clinical stage biopharmaceutical company focused on preventing and treating cytokine storm with lenzilumab, the company's proprietary Humaneered® anti-human granulocyte macrophage-colony stimulating factor (GM-CSF) monoclonal antibody, announced data on the first clinical use of lenzilumab in 12 COVID-19 patients. The manuscript, titled 'First Clinical Use of Lenzilumab to Neutralize GM-CSF in Patients with Severe and Critical COVID-19 Pneumonia' was published online at medRxiv.org (www.medrxiv.org/content/10.1101/2020.06.08.20125369v1). Patients showed rapid clinical improvement with a median time to recovery of five days, median time to discharge of five days and 100% survival to the data cut-off date. Patients also demonstrated rapid improvement in oxygenation, temperature, inflammatory cytokines and key hematological parameters consistent with improved clinical outcomes.

Dr. Zelalem Temesgen, Professor of Medicine at Mayo Clinic and one of the key authors of the study, said, "Lenzilumab use was associated with improved clinical outcomes and oxygen requirement, with no reported mortality. We did not observe any treatment-emergent adverse events attributable to lenzilumab and it was well-tolerated. Based on the pathophysiology of cytokine storm following SARS-CoV-2 infection, along with work conducted at Mayo Clinic on GM-CSF depletion in CAR-T therapy, lenzilumab may offer a rational approach to ameliorate the consequences of cytokine storm in COVID-19."

Dr. Cameron Durrant, chief executive officer of Humanigen, stated, "It is extremely encouraging to see this initial group of high-risk patients with severe and critical COVID-19 pneumonia show clinical improvement on lenzilumab, and at the data cut-off point, 11 of them discharged from the hospital. All 12 patients had at least one risk factor associated with poor outcomes, such as age, smoking history, cardiovascular disease, diabetes, chronic kidney disease, chronic lung disease, high BMI, and elevated inflammatory markers, with several patients having multiple such risk factors."

All patients were hospitalized in the Mayo Clinic system and had severe or critical pneumonia as a result of COVID-19. They were also viewed as being at high risk of further disease progression. All patients required oxygen supplementation and had elevation in at least one inflammatory biomarker prior to receiving lenzilumab. All patients had at least one co-morbidity associated with poor outcomes in COVID-19 and several patients had multiple co-morbidities: 58% had diabetes mellitus, 58% had hypertension, 58% had underlying lung diseases, 50% were obese (defined as a BMI greater than 30), 17% had chronic kidney disease and 17% had coronary artery disease. The median age was 65 years.

More details on the company'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 Phase III potential registration study can be found at clinicaltrials.gov using ClinicalTrials.gov Identifier NCT04351152.

About COVID-19

COVID-19 is an infectious disease caused by SARS-CoV-2. COVID-19 has become a global pandemic, with almost 8 million confirmed cases and almost 450,000 deaths reported to date. Patients with severe cases of COVID-19 experience severe viral pneumonia that can progress to acute respiratory distress syndrome (ARDS), respiratory failure and death.

In severe and critical patients with COVID-19, published research suggests GM-CSF as the key link between pathogenic Th1 cells and inflammatory monocytes, which secrete additional GM-CSF[1].
Lenzilumab is a late clinical-stage, monoclonal antibody targeting GM-CSF, a pro-inflammatory cytokine up-regulated in the serum of COVID-19 patients[2]. The percentages of certain GM-CSF-expressing cells are significantly higher in the blood of ICU-admitted COVID-19 patients compared with healthy controls and are more pronounced in ICU-admitted COVID-19 patients versus non-ICU patients[2].

1. Zhou Y, Fu B, Zheng X, et al. Aberrant pathogenic GM-CSF+ T cells and inflammatory CD14+CD16+ monocytes in severe pulmonary syndrome patients of a new coronavirus. Pre-Print. 2020. https://doi.org/10.1101/2020.02.12.945576.

2. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395(10223):497-506. doi:10.1016/s0140-6736(20)30183-5.

About Humanigen, Inc.

Humanigen, Inc. is developing its portfolio of clinical and pre-clinical therapies for the treatment of inflammation and cancers 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 as well as the serious and potentially life-threatening CAR-T therapy-related side effects while preserving and potentially improving the efficacy of the CAR-T therapy itself, thereby breaking the efficacy/toxicity linkage. The company's immediate focus is to prevent or minimize the cytokine storm that precedes severe lung dysfunction and ARDS in serious cases of SARS-CoV-2 infection and also in combining FDA-approved and development stage CAR-T therapies with lenzilumab, the company's proprietary Humaneered® anti-human-GM-CSF immunotherapy, which is its lead product candidate. A potential registrational Phase III study in COVID-19 patients is currently enrolling. 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). 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 III study and the potential future development of lenzilumab to minimize or reduce the severity of lung dysfunction associated with severe and critical COVID-19 infections or to be approved by FDA for such use or to help CAR-T reach its full potential or to deliver benefit in preventing GvHD. 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 potential need for additional

capital to conduct the Phase III study and grow our business; our dependence on partners to further the development of our product candidates; 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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