First Patient Dosed in FDA-Approved Phase III Lenzilumab Study for COVID-19

First Phase III pivotal study for an anti-GM-CSF therapy in COVID-19 patients

- ***First US randomized, double-blind, placebo-controlled, multi-center, Phase III study with an anti-GM-CSF monoclonal antibody which, if successful, may lead to lenzilumab product approval for COVID-19***
- ***Targeting prevention of serious outcomes in adult, hospitalized patients with COVID-19 pneumonia***

Burlingame, CA, May 6, 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 that the first COVID-19 patient has been dosed in its previously announced Phase III study.

"We are working with some of the top centers and clinicians in the US, alongside our contract research organization partner, CTI, to advance lenzilumab through Phase III with the intent to prevent serious and potentially fatal outcomes in high risk patients who are hospitalized with COVID-19. We are encouraged by our experiences in the compassionate use patients treated with lenzilumab and look forward to working with stakeholders to share these data," said Dr. Cameron Durrant, chief executive officer of Humanigen.

"We are pleased with the speed with which this program has moved through FDA approval and site activation," remarked Tim Schroeder, founder and CEO of CTI.

Dr. Durrant continued, "GM-CSF has been shown to be earlier in the cascade, or 'upstream', of multiple other cytokines, such as IL-6, IL-1 and TNF-α in cytokine storm. Excess GM-CSF production is thought to be the key initial trigger in certain disease states that may lead to significant 'downstream' consequences, as these and other cytokines become elevated. Therefore, the possibility exists that cytokine storm may be prevented or minimized by neutralizing GM-CSF. As the only company working on prevention of cytokine storm through GM-CSF neutralization for nearly three years, we have multiple accepted publications in this field, substantial safety data, including in patients with severe respiratory disease, and have filed extensive IP. We are grateful to FDA, CTI, other partners and our extensive network of recruitment centers in their support to enable recruitment of patients into this study as quickly as possible."

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.

About COVID-19

COVID-19 is an infectious disease caused by SARS-CoV-2. COVID-19 has become a global pandemic, with almost 3.5 million confirmed cases and over 248,000 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 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 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 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 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 clinical collaboration with Kite, a Gilead Company, to evaluate the sequential use of lenzilumab with Yescarta®, axicabtagene ciloleucel, in a multicenter clinical trial in adults with relapsed or refractory large B-cell lymphoma is currently enrolling. 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). For more information, visit www.humanigen.com

About CTI

CTI Clinical Trial and Consulting Services is a global, privately held, full-service contract research organization (CRO), delivering a complete spectrum of clinical trial and consulting services throughout the lifecycle of development, from concept to commercialization. CTI's focused therapeutic approach provides pharmaceutical, biotechnology, and medical device firms with clinical and disease area expertise in rare diseases, regenerative medicine/gene therapy, immunology, transplantation, nephrology, hematology/oncology, neurology, infectious diseases, hepatology, cardiopulmonary, and pediatric populations. CTI also offers a fully integrated multi-specialty clinical research site that conducts phase I-

IV trials. CTI has a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. With clinical trial experience across 6 continents, CTI partners with research sites, patients, and sponsors to fulfill unmet medical needs. CTI is headquartered in the Greater Cincinnati, OH area, with operations across North America, Europe, Latin America, and Asia-Pacific. For more information visit www.ctifacts.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 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 Black Horse Capital and its affiliates owning more than 50% of our outstanding common stock, including their ability to control the company; our lack of profitability and need for additional capital to conduct the Phase III study and operate our business as a going concern; 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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