

Humanigen Expands Phase III Study of Lenzilumab in COVID-19 to Brazil

- Study approval by Brazil's ministry of health follows IND approval granted by the FDA in the US
- Brazil represents an important component of Humanigen's global development program for lenzilumab

Burlingame, CA, August 10, 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 Brazilian regulatory agency, Anvisa, has granted permission to commence a Phase III study of lenzilumab in patients with COVID-19 in Brazil.

This study, now set to begin recruiting patients in Brazil, follows the same protocol approved by the US Food and Drug Administration in April – a multicenter, randomized, placebo-controlled, double-blinded clinical trial focused on hospitalized severe and critical adult COVID-19 patients at high risk of disease progression. Humanigen is working with CTI Clinical Trial & Consulting (CTI), recently named the top global contract research organization for quality, to conduct this trial in Brazil.

Cameron Durrant, MD, MBA, chief executive officer of Humanigen, said, “COVID-19 is a global crisis and we are committed to offering assistance to patients across the world that are impacted by the pandemic. We hope that expanding the study of lenzilumab to research centers in Brazil, a country with surging rates of COVID-19, will offer patients much needed access to a leading COVID-19 therapeutic candidate.”

Currently, Brazil has the second highest reported rates of COVID-19 infection in the world, second only to the US.

“Access to clinical trials is critical for healthcare providers in the fight against COVID-19,” remarked Timothy Schroeder, chief executive officer of CTI. “We are proud to collaborate with our colleagues at Humanigen to extend the reach of the Phase III study of lenzilumab and bring a potential treatment option to those in need.”

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 III potential registration study can be found at clinicaltrials.gov using ClinicalTrials.gov 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.

About CTI Clinical Trial and Consulting Services

CTI Clinical Trial and Consulting Services is a global, privately held, full-service contract research organization (CRO) recently named #1 CRO in the world for quality, 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 surrounding our ongoing and anticipated clinical trial activities in the United States and Brazil and our operational, research, development or commercialization activities for lenzilumab and the other product candidates in our current pipeline. 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 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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