



Humanigen

NEWS RELEASE

Humanigen Completes Enrollment in Phase 3 Study of Lenzilumab in Hospitalized Patients with COVID-19

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BURLINGAME, Calif.--(BUSINESS WIRE)-- **Humanigen, Inc.** (NASDAQ:HGEN) ("Humanigen"), a clinical stage biopharmaceutical company focused on preventing and treating an immune hyper-response called cytokine storm with its lead drug candidate lenzilumab™, today announced it has completed enrollment for its pivotal phase 3 study of lenzilumab for COVID-19. The Company expects to announce top-line data in March 2021.

The primary objective of this Phase 3 randomized, double-blind, placebo-controlled clinical trial, which enrolled 520 patients, is to determine whether lenzilumab in addition to current standard of care can alleviate the immune-mediated cytokine release syndrome (CRS) and improve ventilator-free survival in hospitalized and hypoxic patients with COVID-19 pneumonia.

"Completing enrollment in this Phase 3 study is a significant milestone in the clinical development of lenzilumab," said Cameron Durrant, MD, MBA, chief executive officer of Humanigen. "Therapeutics are an important tool alongside vaccines to tackle the coronavirus. We are grateful to the trial participants, their families, investigators and healthcare professionals for their contributions and partnership in continuing to advance the development of lenzilumab."

Humanigen's investigational treatment lenzilumab, a proprietary Humaneered® anti-human granulocyte macrophage-colony stimulating factor (GM-CSF) monoclonal antibody, is designed to prevent and treat cytokine storm, a complication believed to be a cause of the acute respiratory distress syndrome (ARDS) that can result in invasive mechanical ventilation and death in certain COVID-19 patients. Data showed that almost 90 percent of hospitalized patients with COVID-19 are at risk of this immune hyper-response.

More details on Humanigen's programs in COVID-19 can be found on the company's website under the **COVID-19 tab**. Details on this Phase 3 lenzilumab clinical trial 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. Humanigen believes that its GM-CSF neutralization and gene-editing platform technologies have the potential to reduce the inflammatory cascade associated with coronavirus infection. Humanigen'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. Humanigen 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, Humanigen 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. Humanigen 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 and follow Humanigen on **LinkedIn**, **Twitter** and **Facebook**.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although Humanigen 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 use of lenzilumab to treat patients hospitalized with COVID-19, Humanigen's expectations regarding the timeline for generating top-line data from the Phase 3 study, and statements regarding Humanigen's beliefs relating to any of the other technologies in Humanigen's current pipeline. These forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in Humanigen's lack of profitability and need for additional capital to grow Humanigen's business; Humanigen's dependence on partners to further the development of Humanigen's product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory approvals or authorization for emergency or broader patient use for the product candidate 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 Humanigen'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. Humanigen undertakes 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.

Investors:

Alan Lada

Solebury Trout

alada@troutgroup.com

856-313-8206

Media:

Cammy Duong

Westwicke, an ICR company

Cammy.Duong@Westwicke.com

203-682-8380

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