Humanigen

NEWS RELEASE

Humanigen Reports Positive Phase 3 Topline Results Demonstrating That Lenzilumab™ Improves Survival Without Need for Mechanical Ventilation in Hospitalized Patients With COVID-19

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- Lenzilumab improved the relative likelihood of survival without need for invasive mechanical ventilation (IMV) by 54%, achieving the primary endpoint of the Phase 3 study
- Clinical improvement was observed over and above other treatments, including steroids and/or remdesivir

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 positive topline results from its Phase 3 clinical trial evaluating the efficacy and safety of lenzilumab in patients hospitalized with COVID-19. Trial results showed that patients who received lenzilumab and other treatments, including steroids and/or remdesivir, had a 54% greater relative likelihood of survival without the need for IMV compared with patients receiving placebo and other treatments. These results are statistically significant.

"The results from our Phase 3 clinical trial with lenzilumab treatment were associated with better outcomes in hospitalized hypoxic COVID-19 patients who had not yet progressed to the point of requiring IMV," said Cameron Durrant, MD, MBA, Chief Executive Officer, Humanigen. "Additionally, the trial incorporated a diverse population with various comorbidities, most commonly a body mass index above 30, which is representative of a real-world, high-risk population. Our next step is to submit an application for Emergency Use Authorization (EUA) to the Food and Drug Administration (FDA) as soon as possible. We are also sharing these results with US governmental agencies and other authorities worldwide."

"Mayo Clinic is pleased to have been part of the investigation of lenzilumab from the earliest days of the development program in COVID-19 and are excited by these data," said Andrew Badley, MD, Professor of Infectious Diseases, and Professor and Chair of the Department of Molecular Medicine at Mayo Clinic. "If lenzilumab is

authorized for emergency use by FDA, and based on our clinical trial experience to date, it may then be considered a part of our treatment armamentarium for newly hospitalized patients with COVID-19."

Study results demonstrate that lenzilumab significantly improved patient outcomes. The study achieved its primary endpoint of ventilator-free survival measured through day 28 following treatment (HR: 1.54; 95%CI: 1.03-2.33, p=0.0365). Ventilator-free survival is a validated and reliable measure used in studies that evaluate respiratory distress.1 The Kaplan-Meier estimate for IMV and/or death was 15.6% (95%CI: 11.5-21.0) in the lenzilumab arm versus 22.1% (95%CI: 17.4-27.9) in the placebo arm, representing a 54% improvement in the relative likelihood of survival without the need for IMV. Although this study was not powered to demonstrate a difference in mortality, a favorable trend in mortality was observed: 9.6% (95%CI: 6.4-14.2) in the lenzilumab arm compared with 13.9% (95%CI: 10.1-19.0) in the placebo arm (HR: 1.39; 95%CI: 0.82-2.39; p=0.2287). Approximately 88% of patients received dexamethasone (or other steroids), 62% received remdesivir, and 57% received both, balanced across both arms of the study. Serious adverse events (SAEs) were balanced in both study arms and the SAE profile was similar to that previously documented in prior lenzilumab studies. In this study, lenzilumab appeared to be safe and well-tolerated; no new SAEs were identified, and none were attributed to lenzilumab.

"The data strongly suggest that lenzilumab improved outcomes for hospitalized patients with COVID-19 pneumonia," said Zelalem Temesgen, MD, Professor of Medicine at Mayo Clinic and Principal Investigator of the Phase 3 trial. "The dosing regimen used in this study was specifically designed for hospitalized patients with COVID-19 pneumonia as a potential foundational therapy. Lenzilumab could make the difference between going on a ventilator, which reduces one's chance of survival, and leaving the hospital alive."

"It is impressive to see lenzilumab achieve this milestone. At Emory University, a key center in the National Institutes of Health (NIH) ACTIV-5 study, which is currently enrolling, we are hopeful that lenzilumab will emerge as a valuable therapy for newly hospitalized patients. We believe there may be future opportunities to study lenzilumab in even larger trials, and further explore lenzilumab's impact on mortality rates," added Vincent Marconi, MD, Professor of Medicine at Emory University School of Medicine.

About the Lenzilumab Phase 3 Study

This study was a randomized, double-blind, placebo-controlled, multi-center Phase 3 trial for the treatment and prevention of serious and potentially fatal outcomes in patients who were hospitalized with COVID-19 pneumonia. The primary objective was to assess whether lenzilumab, in addition to other treatments, which included dexamethasone (or other steroids) and/or remdesivir, could alleviate the immune-mediated cytokine release syndrome (CRS) and improve ventilator-free survival. Ventilator-free survival is a composite endpoint of time to death and time to IMV, which is a robust measure that is less prone to favor a treatment with discordant effects on survival or days free of ventilation.1 The trial enrolled 520 patients in 29 sites in the US and Brazil who were at least 18 years of age; experienced blood oxygen saturation (SpO2) of less than or equal to 94%; or required low-flow supplemental oxygen, or high-flow oxygen support, or non-invasive positive pressure ventilation (NIPPV); and were

hospitalized but did not require IMV. Following enrollment, subjects were randomized to receive three infusions of either lenzilumab or placebo, each infusion separated by eight hours over a 24-hour period with other treatments. The primary endpoint was the difference between lenzilumab treatment and placebo treatment in ventilator-free survival through 28 days following treatment. Key secondary endpoints, also measured through 28 days, included ventilator-free days, duration of ICU stay, incidence of invasive mechanical ventilation, extracorporeal membrane oxygenation (ECMO), and/or death, time to death, all-cause mortality, and time to recovery. Results of the trial are planned to be submitted for potential publication in a peer-reviewed journal.

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's immediate focus is to prevent or minimize cytokine release syndrome that precedes severe lung dysfunction in hospitalized and hypoxic patients with COVID-19 pneumonia. Humanigen is also working to create 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.

Humanigen Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are 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 potential request for and receipt of an Emergency Use Authorization from FDA for lenzilumab in COVID-19; and our other plans relating to lenzilumab as a result of the release of the topline results.

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 grow our business; our dependence on partners to further the development of our product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory authorizations and approvals 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 of our latest annual and quarterly reports and other filings with the SEC.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You should not rely upon any forward-looking statements as predictions of future events. We undertake no obligation to revise or update any forward-looking statements made in this presentation to reflect events or circumstances after the date hereof, to reflect new information or the occurrence of unanticipated events, to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, in each case, except as required by law.

For media resources, including product images and fact sheet, please click **here**.

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1 Novack V, Beitler JR, Yitshak-Sade M, Thompson BT, Schoenfeld DA, Rubenfeld G, et al. Alive and Ventilator Free: A Hierarchical, Composite Outcome for Clinical Trials in the Acute Respiratory Distress Syndrome. Critical care medicine. 2020;48(2):158-66

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