Humanigen Reports Additional Analysis of Lenzilumab in Severe and Critical COVID-19 Patients

- **Lenzilumab median time to recovery of five days compares favorably to remdesivir's 10 days in a similar patient group**
- **Lenzilumab Phase 3 potential registration study ongoing in severe and critical COVID-19 patients**
- **Humanigen to host a webinar today at 4:30 p.m. ET to discuss results of the initial cohort of patients treated with lenzilumab**

Burlingame, CA, June 16, 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 additional analysis 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, (https://www.medrxiv.org/content/10.1101/2020.06.08.20125369v2).

A secondary analysis was conducted by Humanigen comparing patients with similar baseline characteristics treated with lenzilumab to patients treated with remdesivir. Results of this analysis are shown in the table below. Patients treated with lenzilumab showed rapid clinical improvement with a median time to improvement of five days and a median time to recovery of five days. In comparison, patients treated with remdesivir demonstrated a median time to improvement of 10 to 11 days and median time to recovery of 10 to 11 days[1]. Remdesivir was granted emergency use authorization based on time to recovery of 11 days in the Adaptive COVID-19 Treatment Trial (ACTT-1)[2].

Patient Baseline Characteristics; Days of Treatment	1 day Lenzilumab	5 day Remdesivir	10 day Remdesivir
Median age (IQR)	65 (52-70)	61 (50-69)	62 (50-71)
Male (%)	67%	60%	68%
Race (%)			
White	75%	71%	70%
Black	0%	10%	12%
Asian	17%	10%	13%
Other	8%	8%	5%
Median BMI (IQR)	29 (24-36)	29 (25-34)	29 (25-33)
Comorbidities			
Diabetes	58%	24%	22%
Hypertension	58%	50%	50%
Asthma	8%	14%	11%
Oxygenation Status			
IMV	-	2%	5%
High-Flow or NIPPV	33%	24%	30%
Low-Flow	67%	56%	54%
Ambient Air	0%	17%	11%
Median days of hospitalization before first dose (IQR)	2 (1-4)	2 (1-3)	2 (1-3)
Clinical Outcome Measures			
Median Time to Improvement	5	10	11
Median Time to Recovery	5	10	11
Clinical Improvement Day 14	100%	64%	54%

The ability of lenzilumab to prevent and/or treat cytokine storm has been previously published[3]. The company believes a combination of lenzilumab to treat cytokine storm and a direct-acting antiviral may be

synergistic in the treatment of patients with COVID-19, given the differing mechanisms of action of these two drug categories.

The results of this additional analysis have several limitations including the small initial cohort treated with lenzilumab, neither data set included a placebo arm, and the inherent problems of making cross trial comparisons. Nevertheless, this secondary analysis was conducted to provide context for the data generated to date with lenzilumab.

Company to Host Conference Call

Humanigen will host a webinar today at 4:30 p.m. ET to discuss the results of the initial cohort of patients treated with lenzilumab. All stakeholders are invited to participate in the call.

To participate on the conference call, please dial (833) 714-0938 from the U.S. or +1 (778) 560-2680 from outside the U.S. The conference ID number is 4442099. A simultaneous webcast of the call and presentation can be accessed by visiting:
https://event.on24.com/wcc/r/2430799/D1BD079E7F6B3E17A5E0A3A7ABD6EA23.

In addition, a replay of the webcast will be available on the company website for 90 days following the event.

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 more than 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[4]. Lenzilumab is a late clinical-stage, monoclonal antibody targeting GM-CSF, a pro-inflammatory cytokine up-regulated in the serum of COVID-19 patients[5]. 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[4].

1. Goldman J, Lye D, et al. Remdesivir for 5 or 10 Days in Patients with Severe Covid-19. New England Journal of Medicine. May 27, 2020. DOI: 10.1056/NEJMoa2015301

2. Beigel J, Tomashek K, et al. Remdesivir for the Treatment of Covid-19-Preliminary Report. New England Journal of Medicine. May 22, 2020. DOI: 10.1056/NEJMoa2007764

3. Sterner R, Sakemura R, et al. GM-CSF inhibition reduces cytokine release syndrome and neuroinflammation but enhances CAR-T cell function in xenografts. Blood. February 14, 2019. doi: 10.1182/blood-2018-10-881722

4. 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.

5. 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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