Humanigen

NEWS RELEASE

FDA has declined Humanigen's Emergency Use Authorization (EUA) Request for Lenzilumab in Hospitalized COVID-19 Patients

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- FDA has committed to working with Humanigen in the development of lenzilumab and has invited Humanigen to submit additional data as it becomes available
- NIH's ACTIV-5/BET-B study is expected to provide further data that may support a new EUA request
- Humanigen remains committed to completing regulatory processes underway seeking Marketing Authorization for lenzilumab to treat hospitalized COVID-19 patients in the U.K. and other territories

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,' announced today the U.S. FDA has declined its request for emergency use authorization of lenzilumab to treat newly hospitalized COVID-19 patients. In its letter, FDA stated that it was unable to conclude that the known and potential benefits of lenzilumab outweigh the known and potential risks of its use as a treatment for COVID-19.

"We remain committed to bringing lenzilumab to patients hospitalized with COVID-19," said Cameron Durrant, MD, Chief Executive Officer, Humanigen. "We believe the ongoing ACTIV-5/BET-B trial, which has been advanced to enroll up to 500 patients, may provide additional safety and efficacy data sufficient to support our efforts to obtain an EUA to treat hospitalized COVID-19 patients."

About Humanigen

Humanigen, Inc. (Nasdaq: HGEN) ("Humanigen"), a clinical-stage biopharmaceutical company focused on preventing and treating an immune hyper-response called 'cytokine storm'. Lenzilumab is a first-in class antibody that binds to and neutralizes granulocyte-macrophage colony-stimulating factor (GM-CSF). Results from preclinical models indicate GM-CSF is an upstream regulator of many inflammatory cytokines and chemokines involved in the cytokine storm. Early in the COVID-19 pandemic, investigation showed high levels of GM-CSF secreting T cells were

associated with disease severity and intensive care unit admission. Humanigen's Phase 3 LIVE-AIR study suggests early intervention with lenzilumab may prevent consequences of a full-blown cytokine storm in hospitalized patients with COVID-19. Humanigen has submitted lenzilumab to Medicines and Health Regulatory Agency in the United Kingdom for a rolling review towards potential Marketing Authorization. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with COVID-19, CD19-targeted CAR-T cell therapies and exploring the effectiveness of lenzilumab in other inflammatory conditions such as acute Graft versus Host Disease in patients undergoing allogeneic hematopoietic stem cell transplantation, eosinophilic asthma, and rheumatoid arthritis. For more information, visit **www.humanigen.com** and follow Humanigen on LinkedIn, Twitter, and Facebook.

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 the sufficiency of the data from the ACTIV-5/BET-B study to warrant a future submission of a new EUA request; statements regarding our efforts to request and receive Marketing Authorization or Conditional Marketing Authorization for lenzilumab in COVID-19 in the U.K. and other territories; and our other plans relating to lenzilumab.

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.

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