Humanigen

NEWS RELEASE

Humanigen Reports Positive Data With Lenzilumab in the ZUMA-19 CAR-T Phase 1b Study in DLBCL and Plans to Initiate a Potential Registrational Study

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- At the recommended Phase 2 dose, lenzilumab in combination with CAR-T, demonstrated a 100% objective response rate (ORR) and no severe cytokine release syndrome or severe neurotoxicity
- Lenzilumab reduced IL-6, CRP, ferritin, MCP-1, IL-8, and IP-10 (CXCL-10) among others
- Humanigen now plans to conduct a randomized, potentially registrational, Phase 2 study with lenzilumab combined with all commercially available CD19 CAR-T therapies in DLBCL
- Humanigen has terminated the ZUMA-19 clinical collaboration agreement with Kite, a Gilead Company

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 data from the Phase 1b portion of ZUMA-19 evaluating the efficacy and safety of lenzilumab in patients treated with CAR-T in diffuse large B-cell lymphoma (DLBCL). At the recommended Phase 2 dose of lenzilumab, the ORR was 100% and no patient experienced severe cytokine release syndrome (CRS) or severe neurotoxicity (NT).

ZUMA-19 was a clinical study designed to evaluate the efficacy and safety of lenzilumab and CAR-T (axicabtagene ciloleucel, Axi-Cel) in patients with relapsed or refractory DLBCL.

This study was a standard 3+3 design with three patients administered 600 mg lenzilumab (cohort 1) and three patients administered 1,800 mg lenzilumab (cohort 2) just prior to CAR-T. The recommended Phase 2 dose was determined to be 1,800 mg.

In the six study patients, the ORR was 83% (n=5) which included four complete responses (CR). In cohort 1, there was no severe CRS (≥ grade 3). One patient experienced grade 3 NT with a two-day duration. At the recommended Phase 2 dose (cohort 2), ORR was 100% (n=3) and the toxicity-free CR (CRS and NT < grade 2) was 66% (n = 2). There

was no severe CRS or severe NT at the recommended Phase 2 dose. There were no adverse events attributed to lenzilumab across the study.

Inflammatory markers were correlated with reduced rates of CRS and NT. Lenzilumab dose-dependently reduced myeloid cytokines IL-6, IL-8, MCP-1, and IP-10 (CXCL-10) and systemic inflammatory markers CRP, ferritin, and SAA.

“These encouraging results from ZUMA-19 provide further proof of concept that lenzilumab may break the linkage between efficacy and toxicity (CRS and NT) widely-associated with CAR-T, and may improve durability of response,” said Dale Chappell, MD, MBA, Chief Scientific Officer, Humanigen. “We believe these data warrant a larger study involving multiple CAR-T therapies.”

Humanigen will initiate a randomized, multicenter, potentially registrational, Phase 2 study to evaluate the efficacy and safety of lenzilumab combined with all commercially available CD19 CAR-T therapies in DLBCL. The study plans to enroll approximately 150 patients and the protocol is being submitted to FDA.

Humanigen has terminated the clinical collaboration agreement with Kite related to ZUMA-19 and both parties will collaborate to wind down current study activities.

“Humanigen is pleased to be in a position to proactively develop lenzilumab across the CAR-T landscape and further expand its pipeline,” said Cameron Durrant, MD, MBA, Chief Executive Officer, Humanigen. “We thank Kite for their sponsorship and contribution that has allowed Humanigen to progress to this exciting point.”

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 Acute Respiratory Distress Syndrome (ARDS) in cases of SARS-CoV-2 infection and has completed a 520 patient Phase 3 study. 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. Lenzilumab is the first and only anti-human GM-CSF treatment to be tested in the NIH ACTIV-5/BET-B clinical trial. Lenzilumab is being investigated in combination with remdesivir and will be compared with remdesivir alone. Two hundred hospitalized patients 18 years old and greater who need medical care for COVID-19 infection will be enrolled and randomized, half of whom will receive lenzilumab. The evaluation of lenzilumab in this Phase 2 trial began in October 2020 and is expected to be completed in the second half of 2021. 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). 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 Humanigen's beliefs relating to the technologies in Humanigen's 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 potential 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 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 press release 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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