GM-CSF Gene-Edited CAR-T Data to be Presented at International Society for Cell & Gene Therapy Annual Meeting 2021

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BURLINGAME, Calif.--(BUSINESS WIRE)-- Humanigen, Inc. (Nasdaq: HGEN), 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 that granulocyte macrophage-colony stimulating factor (GM-CSF) gene-edited CAR-T data will be presented at the International Society for Cell & Gene Therapy (ISCT) 2021 Annual Meeting which will be held in New Orleans from May 26-28, 2021.

Researchers at the Mayo Clinic, Rochester, MN have demonstrated that CRISPR/Cas9 GM-CSF knock-out in CAR-T cells (GM-CSF KO CAR-T) dampens CAR-T cell early activation and reduces activation-induced cell death (AICD), resulting in enhanced antigen-specific T-cell expansion in vivo. The modulation of intrinsic pathways is not due to an off-target effect and provides additional mechanistic rationale for the improved anti-tumor activity observed with GM-CSF KO CAR-T.

“These findings highlight the intrinsic value of GM-CSF KO CAR-T as a novel, potentially more effective and less toxic platform to enhance current CAR-T cell therapies,” said Cameron Durrant, MD, MBA, chief executive officer of Humanigen.

Mayo Clinic researchers will present their research entitled, “GM-CSF disruption in CAR-T cells ameliorates CAR-T cell activation and reduces activation-induced cell death,” on May 28, 2021 from 11:30 AM to 1:00 PM ET as part of the session titled “Novel Allo-Engineering Approaches and Progress in Off-the-Shelf Products.”

“Mayo Clinic is enthusiastic about these findings, and they provide us with valuable information to enhance our current CAR-T cell therapies,” said Saad S. Kenderian, MD, Division of Hematology, Mayo Clinic.

Details for the upcoming event are below:
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 on the development of lenzilumab as a therapy for hospitalized, hypoxic COVID-19 patients. Humanigen recently announced plans to 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 diffuse large B-cell lymphoma.

Humanigen is also focused on creating next-generation combinatorial 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). 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 timing for submission of applications for EUA and BLA, and for conditional marketing authorization in the UK and EU, as well as 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 the company's lack of profitability and potential need for additional capital to grow its business; its dependence on partners to further the development of its 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 and elsewhere in 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 rely upon any forward-looking statements as predictions of future events. The company undertakes 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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