Humanigen Announces Completion of Enrollment in Phase 1 Study of Ifabotuzumab in Glioblastoma Multiforme

Burlingame, CA, December 17, 2020 – Humanigen, Inc. (NASDAQ: HGEN) (“Humanigen”), a clinical stage biopharmaceutical company developing its portfolio of clinical and pre-clinical therapies for the treatment of cancers and infectious diseases, today announced completing enrollment in its Phase 1 bioimaging study of ifabotuzumab in patients with recurrent glioblastoma multiforme (GBM). Ifabotuzumab, or ifab, is the Company’s proprietary anti-EphA3 monoclonal antibody. This trial is supported by funding from the Cure Brain Cancer Foundation. Results from the study, being conducted at the Olivia Newton-John Cancer Research Institute in Heidelberg, Victoria, Australia, are expected in the first half of 2021.

“GBM represents an extremely aggressive form of cancer that has historically eluded effective treatment, and we remain committed to investigating ifabotuzumab as a potential new approach to treat this devastating disease as well as other solid tumors,” said Prof. Andrew Scott, Head, Tumor Targeting Laboratory, Olivia Newton-John Cancer Research Institute, Professor, School of Cancer Medicine, La Trobe University and a member of the Australian Brain Cancer Mission Strategic Advisory Group.

GBM is the most frequent and lethal type of primary brain cancer, with only 10% of patients surviving five years, and preclinical research has shown that EphA3 is responsible for maintaining less differentiated, tumor-initiating cells. Ifabotuzumab is a non-fucosylated IgG1K antibody designed to bind to EphA3, which is expressed in 38-40% of GBM and 100% of the tumor vasculature and is widely expressed in the tumor stroma and tumor vasculature of other solid tumors.

The primary goal of the Phase 1 study is to evaluate safety of ifabotuzumab and to recommend a dose for a potential Phase 2 study either with ifabotuzumab or an antibody drug conjugate (ADC) based on ifabotuzumab. Led by Prof. Andrew Scott and Prof. Hui Gan, the study uses radiolabelled ifabotuzumab followed by sequential positron emission tomography (PET) imaging to determine biodistribution, frequency of in situ EphA3 expression and quantitative tumor uptake of ifabotuzumab. Subsequently, patients were enrolled into one of three cohorts evaluating escalating doses of ifabotuzumab administered on a weekly basis, allowing for an assessment of receptor occupancy, response rate and overall survival.

“The study has now completed recruitment and we are very excited at having shown that ifabotuzumab is able to target the brain tumor in all the patients tested without binding to healthy tissue,” said Prof. Hui Gan, Clinical Research Lead, Olivia Newton-John Cancer Research Institute and Director, Cancer Clinical Trials Center, Austin Health. “We saw some signs that ifabotuzumab was affecting the blood vessels that feed the tumors and may halt their ability to grow in some patients.”

“There is a tremendous need to advance new therapies for solid tumors and we look forward to progressing the clinical development of ifabotuzumab,” said Cameron Durrant, MD, MBA, Chief Executive Officer, Humanigen, Inc.

Humanigen. “Ifabotuzumab represents an important part of our immuno-oncology arsenal as we advance our pipeline to target a wide-range of cancers.”

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. We believe that our GM-CSF neutralization and gene-editing platform technologies have the potential to reduce the inflammatory cascade associated with coronavirus infection. The company’s immediate focus is to prevent or minimize the cytokine release syndrome that precedes severe lung dysfunction and ARDS in serious cases of SARS-CoV-2 infection. The company 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, the company 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. 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). 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.

About the Olivia Newton-John Cancer Research Institute

The Olivia Newton-John Cancer Research Institute is a leader in the development of experimental and breakthrough cancer treatments. We investigate and develop treatments for cancers of the breast, bowel, lung, melanoma, prostate, liver, gastrointestinal tract and brain. Our researchers and clinicians are running more than 200 clinical trials, giving patients access to potential new treatments including immunotherapies and personalised medicine. For more information visit www.onjcri.org.au.

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 the Phase 1 trial results, expected commencement and design of a Phase 2 trial, and statements regarding our beliefs relating to any of the other technologies in our 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 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 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 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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