Humanigen and Avid Bioservices Enter Into cGMP Manufacturing Agreement for COVID-19 Therapeutic Candidate Lenzilumab in Support of Potential EUA Filing

February 3, 2021

BURLINGAME, Calif. & TUSTIN, Calif.--(BUSINESS WIRE)--Feb. 3, 2021-- Avid Bioservices, Inc. (NASDAQ:CDMO) (NASDAQ:CDMOP) ("Avid") and Humanigen, Inc. (NASDAQ:HGEN) ("Humanigen") today announced that they have entered into a manufacturing services agreement to expand production capacity for lenzilumab ™, Humanigen's therapeutic candidate in development for COVID-19. Lenzilumab is an anti-human granulocyte macrophage-colony stimulating factor (GM-CSF) monoclonal antibody designed to prevent and treat an immune hyper-response called "cytokine storm" associated with COVID-19. Humanigen has completed enrollment of its 520 patient Phase 3 clinical trial of lenzilumab in hospitalized COVID-19 patients.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210203005204/en/

Under the terms of this Current Good Manufacturing Practice (cGMP) agreement, Avid will initiate technical transfer and analytical validation activities for lenzilumab with the goal of delivering cGMP drug substance batches to support Humanigen's regulatory and potential commercial activities. This collaboration enhances commercial production efforts for lenzilumab in advance of potential filings for emergency use authorization (EUA) and subsequent Biologics License Application (BLA) later this year.

"Having recently completed enrollment in our Phase 3 clinical trial of lenzilumab, we are also focusing on scalable manufacturing capacity to help ensure access in advance of a potential EUA filing," said Cameron Durrant, MD, MBA, chief executive officer of Humanigen.

"As the COVID-19 pandemic continues to rage in the U.S. and around the world, it is essential that life science companies like Avid and Humanigen align our areas of expertise to speed the development and commercialization of valuable therapeutics that can make a difference in the lives of patients. At Avid, we are proud to play our part in these important efforts," said Timothy Compton, chief commercial officer of Avid. "Lenzilumab is an exciting COVID-19 therapeutic candidate and the type of complex biologic for which Avid possesses decades of manufacturing success. We are pleased to be trusted by Humanigen to provide the critical CDMO services that will be essential for achieving the company's regulatory and commercialization goals for lenzilumab."

About Avid Bioservices, Inc.

Avid Bioservices is a dedicated contract development and manufacturing organization (CDMO) focused on development and cGMP manufacturing of biopharmaceutical drug substances derived from mammalian cell culture. The company provides a comprehensive range of process development, cGMP clinical and commercial manufacturing services for the biotechnology and biopharmaceutical industries. With 28 years of experience producing monoclonal antibodies and recombinant proteins, Avid's services include cGMP clinical and commercial drug substance manufacturing, bulk packaging, release and stability testing and regulatory submissions support. For early-stage programs the company provides a variety of process development activities, including upstream and downstream development and optimization, analytical methods development, testing and characterization. The scope of our services ranges from standalone process development projects to full development and manufacturing programs through commercialization. www.avidbio.com

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 ARDS in serious cases of SARS-CoV-2 infection. 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. 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). 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 and follow Humanigen on LinkedIn, Twitter and Facebook.

Avid Bioservices Forward-Looking Statements

Statements in this press release which are not purely historical, including statements regarding Avid Bioservices, Inc.'s intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties including, but not limited to, the risk that Humanigen does not receive EUA and/or BLA approval and the risk that the company, as part of a larger manufacturing network, may not be a significant source of commercial supply following a BLA approval, if any. Our business could be affected by a number of other factors, including the risk factors listed from time to time in our reports filed with the Securities and Exchange Commission including, but not limited to, our annual report on Form 10-K for the fiscal year ended April 30, 2020 and subsequent quarterly reports on Form 10-Q, as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. We caution investors not to place undue reliance on the forward-looking statements contained in this press release, and we disclaim any obligation, and do not undertake, to update or revise any forward-looking

statements in this press release except as may be required by law.

Humanigen Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although Humanigen 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 use of lenzilumab to treat patients hospitalized with COVID-19, Humanigen's expectations regarding the timeline to file for EUA, as well as a potential BLA filing, statements regarding Humanigen's ability to scale the manufacturing of lenzilumab, and statements regarding Humanigen's beliefs relating to any of the other technologies in Humanigen's current pipeline. These forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the risks inherent in Humanigen's lack of profitability and need for additional capital to grow Humanigen's business; Humanigen's dependence on partners to further the development of Humanigen's product candidates; the uncertainties inherent in the development, attainment of the requisite regulatory approvals or authorization for emergency or broader patient use for the product candidate 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 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 place undue reliance on any forward-looking statements, which speak only as of the date of this release. Humanigen undertakes 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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Source: Humanigen, Inc. and Avid Bioservices, Inc.