Humanigen

NEWS RELEASE

Humanigen Reports Third Quarter and Nine Months Ending September 30, 2021 Financial Results and Provides Corporate Update

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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 provided a corporate and regulatory update and reported financial results for the third quarter and nine months ended September 30, 2021.

Status of Application to UK's Medicines and Healthcare Products Regulatory Agency (MHRA)

On June 11, 2021, Humanigen initiated submission of an application seeking Conditional Marketing Authorization (CMA) from the UK's MHRA for lenzilumab in hospitalized COVID-19 patients and it was accepted for expedited COVID-related rolling review on July 9, 2021. Humanigen submitted the last of the planned modules on September 30, 2021. The company believes MHRA is actively reviewing its application.

"We are continuing our efforts to get lenzilumab to hospitalized COVID-19 patients. The recent selection of lenzilumab by the European Commission as one of the 10 most promising treatments for COVID-19, validates our view that lenzilumab offers meaningful clinical potential.1 We appreciate the commitment MHRA has made to reviewing our application," said Cameron Durrant, Chairman and CEO, Humanigen. "The vaccination rate in the UK is 79%, yet hospitalizations due to COVID-19 continue. We continue to work with regulators in the UK, US, and European Union to potentially bring this therapy to patients."2

Recent data suggests that the protection offered to fully vaccinated individuals from infection and severe disease wanes over time and there is a continued need for additional treatment options for patients who become severely ill after infection with SARS-CoV-2.3 Despite nearly 80% of the population in the UK being fully vaccinated, there were nearly 25,000 COVID-19 patients newly admitted to hospitals for treatment in October, more than 60% of whom were fully vaccinated. 2,4,5

Timothy Morris, COO/CFO, Humanigen, noted, “We are preparing for potential launch in the UK if lenzilumab were to receive authorization from MHRA by securing a supply chain to import, release and distribute lenzilumab to UK hospitals. Separately, our agreement with Clinigen, once fully operational, will allow us to distribute lenzilumab to patients in 16 countries in the EU where regulations allow for managed access, named patient, compassionate use or similar programs. We are also pleased by the progress being made to evaluate lenzilumab in Chronic Myelomonocytic Leukemia (CMML), acute Graft versus Host Disease (aGvHD), and our own effort to conduct a Phase 3 study with commercially-approved CD19 CAR-T therapies in non-Hodgkin lymphoma (NHL).”

Third Quarter and Recent Highlights:

Lenzilumab in hospitalized COVID-19

- European Commission selected Humanigen’s lenzilumab as one of the 10 most promising treatments for COVID-19.
- Submitted final required modules as well as a risk management plan and pediatric investigation plan for CMA for lenzilumab in COVID-19 to the UK’s MHRA.
- EMA appointed a Rapporteur and Co-Rapporteur related to the company’s planned submission of an MAA for lenzilumab in COVID-19 in the EU.
- Entered into agreement with Clinigen Group to establish a Managed Access Program to enable access to lenzilumab on a case-by-case basis to patients in up to 16 European countries.
- Requested and granted a Type B meeting with FDA. Included in the briefing materials for the meeting request were day 60 data as well as detailed CRP analysis from the company’s LIVE-AIR Phase 3 study.

Lenzilumab in CMML, aGvHD, and NHL

- First patient dosed in Phase 2 study of lenzilumab in patients with Chronic Myelomonocytic Leukemia (CMML), sponsored by the company’s Australian partners.
- Reached agreement with University of Birmingham to conduct a Phase 2/3, potentially registrational, trial to evaluate lenzilumab in the treatment of aGvHD at IMPACT Partnership stem cell transplant centers across the UK.
- Scheduled a meeting in December 2021 with FDA to discuss a protocol to conduct a Phase 3 randomized, placebo-controlled, open-label trial of lenzilumab to improve the safety and efficacy of CD19 CAR-T therapies in the treatment of NHL.

Corporate

- Elected John Hohneker, MD, and Kevin Xie, PhD, to Board of Directors.
- Received U.S. Patent 11,130,805 protecting the method of treating CAR-T cell therapy-induced neurotoxicity using a GM-CSF inhibitor. The patent issued on September 28, 2021 and has an expected patent term through October 2, 2038.

ACTIV-5 Update

In August 2021, the National Institutes of Health (NIH) announced the advancement of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV-5) and Big Effect Trial, in the "B" arm of the trial (BET-B), referred to as ACTIV-5/BET-B. Following feedback from and consultation with the company, the NIH advanced the study to a Phase 2/3 study with target enrollment of up to 400 patients with a baseline CRP<150 mg/L, or a total of up to 550 patients, and amended the protocol for ACTIV-5/BET-B in a manner that aligns with the design of the company's LIVE-AIR trial. The trial is approximately 75% enrolled.

Third Quarter and Nine Months Ended September 30, 2021 Financial Results

Net loss for the three months ended September 30, 2021 was $66.7 million or $1.12 per share as compared to $30.8 million or $0.71 per share for the three months ended September 30, 2020. The net loss for the nine months ended September 30, 2021 was $203.1 million or $3.56 per share as compared to $57.2 million or $1.79 per share for the nine months ended September 30, 2020. The increase in net loss for both periods was largely due to an increase in total expenses, mainly Research and Development ("R&D") expense which rose significantly as the company accelerated its efforts to manufacture lenzilumab for potential commercialization upon receipt of a regulatory authorization. R&D expense increased $38.4 million from $22.4 million for the three months ended September 30, 2020, to $60.8 million for the three months ended September 30, 2021, and increased $139.6 million from $44.2 million for the nine months ended September 30, 2020, to $183.8 million for the nine months ended September 30, 2021. The manufacturing expense included in R&D was $55.8 million for the third quarter of 2021 as compared to $10.9 million for the prior year quarter, and $162.9 million for the nine months ended September 30, 2021, as compared to $28.3 million for the prior year period. Manufacturing expense is comprised of technical transfer, start-up and production expenses for bulk drug substance (BDS) and drug product (DP). The company has built an extensive network of contract manufacturing organizations (CMOs) to produce lenzilumab BDS, to fill DP, and to establish a supply chain for lenzilumab.

On September 8, 2021, FDA declined the company's Emergency Use Authorization (EUA) request for lenzilumab in hospitalized COVID-19 patients. Subsequently, the company has amended, and in some cases canceled, certain of its manufacturing agreements, some of which were contingent on EUA, in an effort to reduce its future spending on lenzilumab production until and if authorization is received in the UK, EU, or US. In the event of authorization by MHRA, EMA, or FDA, the company anticipates that the demand for commercial product could exceed the in process and planned production of lenzilumab through 2022. The company intends to seek additional manufacturing capacity if authorization is obtained. Production beyond 2022 would require the company to secure capacity at our CMOs and acquire the necessary supplies and components. The Company expects to use a portion of the revenues generated from commercial sale of lenzilumab following receipt of a regulatory authorization to support its efforts to expand production capacity in 2023 and beyond.

Certain of the company's CMOs have been unsuccessful in their efforts to manufacture some batches of lenzilumab to the company's specifications for various reasons. The company is working with these CMOs to determine if batches of BDS manufactured by them may be usable in the future or, if not, whether other financial recompense will be offered to the company.

Cash and Cash Equivalents

Net cash used in operating activities, net of balance sheet changes, was $48.0 million for the three months ended September 30, 2021, and $151.8 million for the nine months ended September 30, 2021. During the nine months ended September 30, 2021, the company raised net proceeds of $40.0 million from the sale of shares of common stock under its At-the-Market offering program, drew $25.0 million under its credit facility with Hercules Capital, providing net proceeds of $24.4 million, and completed a public offering of common stock with net proceeds of $94.2 million. As of September 30, 2021, the company had cash and cash equivalents of $76.5 million. Subsequent to September 30, 2021, the company received net proceeds of approximately $24.5 million under its At-the-Market offering program.

A summary of key financial highlights as of and for the three and nine months ended September 30, 2021 and 2020 is as follows ($ in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
License revenue	$ 1,036	$ -	$ 2,558	$ -
Research and development	60,811	22,416	183,757	44,218
General and administrative	6,204	8,331	19,228	11,685
Loss from operations	(65,979)	(30,747)	(200,427)	(55,903)
Net loss	$ (66,739)	$ (30,751)	$ (203,109)	$ (57,240)
Net loss per common share	$ (1.12)	$ (0.71)	$ (3.56)	$ (1.79)
Weighted average common shares	59,486,626	43,490,071	56,997,039	32,041,790

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 76,500	$ 67,737
Current assets	$ 77,847	$ 68,212
Current liabilities	68,709	20,415
Working capital	$ 9,138	$ 47,797

About Humanigen, Inc.

Humanigen, Inc. (Nasdaq: HGEN) (Humanigen), is 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 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 Conditional Marketing Authorization. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with COVID-19 and CD19-targeted CAR-T cell therapies and is also 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: Humanigen's beliefs as to the potential benefits of lenzilumab as a treatment for hospitalized COVID-19 patients; its efforts to request and receive Conditional Marketing Authorization for lenzilumab in COVID-19 in the UK and other territories; its beliefs and projections regarding the need for lenzilumab as a therapeutic if authorized or approved; the company's projections for anticipated supply of lenzilumab through the end of 2022; the effectiveness of its preparations to commercialize lenzilumab in the UK and other markets, if CMA or other marketing approval were granted; its efforts to mitigate its manufacturing expenses in future periods pending receipt of a marketing authorization or approval from a regulatory agency such as MHRA, EMA or FDA; its ability to resolve payment disputes with certain of its CMOs and other service providers on favorable terms; and its other plans to initiate or participate in planned clinical trials and otherwise explore the effectiveness of lenzilumab and other candidates in its development portfolio as therapies for other inflammation and immune-oncology indications.

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 need for additional capital to conduct 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; challenges associated with manufacturing and commercializing a biologic such as lenzilumab; 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 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.

References

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Humanigen Investor Relations

Ken Trbovich

Humanigen

trbo@humanigen.com

650-410-3206

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