Humanigen

NEWS RELEASE

Humanigen Reports Year-End 2021 Financial Results

2/28/2022

SHORT HILLS, N.J.--(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 reported financial results for the year ended December 31, 2021, and announced corporate objectives for 2022.

Cameron Durrant, chairman and chief executive officer of Humanigen stated, “We initiated the development of lenzilumab, or LENZ®, in May 2020 as a treatment for hypoxic COVID-19 patients. The virus and the treatment landscape continue to evolve. We believe that COVID-19 will become a serious endemic disease and will continue to impact society, healthcare systems and patients and that, if authorized or approved by regulatory agencies, LENZ, a variant-agnostic immunomodulatory antibody, could address a significant unmet need in COVID-19 for the foreseeable future. Humanigen made significant progress in developing lenzilumab over the last year, highlighted by the completion of our phase 3 study of lenzilumab in COVID-19, LIVE-AIR, and the publication of positive results from the study in The Lancet Respiratory Medicine, a world-renowned, peer-reviewed journal.”

“We look forward to the announcement of the topline data from a second phase 2/3 study of lenzilumab in COVID-19, the ACTIV-5/BET-B study conducted by the National Institutes of Health, in late Q1 or early Q2. If results from ACTIV-5/BET-B in patients with a baseline C-reactive protein level less than 150mg/L build on the data from LIVE-AIR published in The Lancet, we plan to prepare and submit an amendment to our application for emergency use authorization for lenzilumab in hospitalized COVID-19 patients to the FDA, as well as regulatory submissions in the European Union and United Kingdom,” Dr. Durrant continued.

Lenzilumab is an investigational product and is not currently authorized or approved in any country.

Highlights over the past year include:

Lenzilumab in COVID-19 patients

- Completed the LIVE-AIR study, which showed that patients who received lenzilumab and other treatments, including steroids and/or remdesivir, had a 54% greater relative likelihood of survival without the need for invasive mechanical ventilation compared with patients receiving standard of care and placebo.
- Positive results of the LIVE-AIR study were published in The Lancet Respiratory Medicine, **https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00494-X/fulltext**. The Lancet publication concluded that lenzilumab treatment of patients with COVID-19 can improve the likelihood of survival without the need for mechanical ventilation, with a safety profile comparable to placebo.
- Completed enrollment of the Phase 2/3 ACTIV-5/BET-B study, sponsored by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, and enrolled over 400 patients in the primary analysis population (patients with a C-reactive protein level at baseline of less than 150mg/L).
- FDA has guided that, if the trial is successful, the company can include the results from ACTIV-5/BET-B in an amended Emergency Use Authorization (EUA) submission for lenzilumab for the treatment of patients with COVID-19.

Lenzilumab in DLBCL, NHL, aGvHD, and CMML

- 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 overall response rate (ORR) was 100% and no patient experienced severe neurotoxicity (NT) or severe cytokine release syndrome (CRS).
- FDA provided guidance on the registration pathway for lenzilumab for the prevention of CAR-T therapy related toxicities including Immune Effector Cell-Associated Neurotoxicity (ICANS), which Humanigen intends to study in the registrational Phase 3 SHIELD study.
- Planning to enroll the first patient in the first half of 2022 in a Phase 2/3, potentially registrational study (the RATinG study) to evaluate lenzilumab in the treatment of aGvHD at IMPACT Partnership stem cell transplant centers across the UK.
- First patient dosed in Phase 2 study of lenzilumab (the PREACH-M study) in patients with Chronic Myelomonocytic Leukemia (CMML), sponsored by the company's Australian partners.

2022 Objectives Include:

- Announcing topline results from ACTIV-5/BET-B in COVID-19
- Filing amended EUA with FDA for lenzilumab in COVID-19 in the US
- Responding to MHRA requests for additional information on lenzilumab for the CMA in COVID-19 in the UK
- Filing CMA for lenzilumab in COVID-19 under Accelerated Approval with EMA in the EU
- Commencing shipments under LenzMAP, the lenzilumab managed access program for COVID-19 in the UK and multiple European countries
- Continuing enrollment in the PREACH-M CMML study in Australia
- Initiating the SHIELD Phase 3 registrational CAR-T study in the US
- Initiating the RATinG Phase 2/3 potentially registrational aGvHD study in the UK

- Initiating the C-SMART (COVID in cancer patients) study in Australia

Year Ended December 31, 2021 Financial Results

Net loss for the year ended December 31, 2021 was $236.6 million or $4.04 per share as compared to $89.5 million or $2.42 per share for the year ended December 31, 2020. The increase in net loss for the year was due to an increase in total expenses, mainly Research and Development (R&D) expense. R&D expense increased $140.4 million from $72.7 million for the year ended December 31, 2020, to $213.1 million for the year ended December 31, 2021. The increase is primarily due to an increase of $143.9 million in lenzilumab manufacturing costs, including consulting fees, and a $1.7 million increase in internal costs, primarily compensation-related, partially offset by a $5.2 million reduction in clinical trial expenses for lenzilumab.

Cash and Cash Equivalents

Net cash used in operating activities, net of balance sheet changes, was $184.0 million for the year ended December 31, 2021. During the year ended December 31, 2021, the company raised net proceeds of $65.7 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, which provided net proceeds of $24.4 million, and completed a public offering of common stock with net proceeds of $94.2 million. As of December 31, 2021, the company had cash and cash equivalents of $70.0 million. Subsequent to December 31, 2021, the company raised net proceeds of approximately $3.7 million under its At-the-Market offering program.

A summary of key financial highlights as of and for the years ended December 31, 2021 and 2020 is as follows ($ in thousands):

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
License revenue	$ 1,037	$ 312	$ 3,595	$ 312
Research and development	29,358	28,495	213,115	72,713
General and administrative	4,024	4,112	23,252	15,797
Loss from operations	(32,345)	(32,295)	(232,772)	(88,198)
Net loss	$ (33,540)	$ (32,295)	$ (236,649)	$ (89,535)
Net loss per common share	$ (0.53)	$ (0.63)	$ (4.04)	$ (2.42)
Weighted average common shares	63,136,915	51,619,695	58,533,637	36,963,030

	December 31, 2021	December 31, 2020

Cash and cash equivalents	$ 70,016	$ 67,737
Current assets	$ 70,971	$ 68,212
Current liabilities	68,725	20,415
Working capital	$ 2,246	$ 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. 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 and in 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; the timeline for announcement of release of topline results from the ACTIV-5/BET-B study being conducted by NIH; its efforts and potential timeline to make future regulatory submissions in respect of potential emergency use authorization from FDA or a marketing authorization or approval from FDA, MHRA or EMA for commercial use of lenzilumab in COVID-19 patients; 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 as a going concern; 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 (including EUA in the United States and CMA in the United Kingdom and European Union) 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 or arbitration; 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.

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Source: Humanigen, Inc.