Humanigen

NEWS RELEASE

Humanigen Reports First Quarter 2021 Financial Results

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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 reported financial results for the first quarter ending March 31, 2021 and provided a regulatory update on lenzilumab.

"We are encouraged by the achievements Humanigen has made since the beginning of 2021 and by our progress on the emergency use authorization application," stated Cameron Durrant, MD, MBA, Chief Executive Officer, Humanigen. "We successfully completed our Phase 3 study of lenzilumab, referred to as LIVE-AIR, for the treatment of newly hospitalized and hypoxic COVID-19 patients. Trial results 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 IMV compared with patients receiving placebo and other treatments. We believe this statistically significant result, along with data regarding additional endpoints and further analysis from the study, support the submission of applications for emergency use authorization to the U.S. Food and Drug Administration and conditional marketing authorization in the United Kingdom and the European Union. As is typical with COVID-19 study results, a pre-print of the LIVE-AIR study was published on-line. Positive results from the Phase 1b study of lenzilumab in combination with CAR-T gave further encouragement to our therapeutic approach to breaking the linkage between efficacy and toxicity in CAR-T, and we are designing a Phase 2 study of lenzilumab combined with all commercially available CD19 CAR-T therapies in diffuse large B-cell lymphoma patients."

Highlights from the First Quarter of 2021 Include:

Clinical – Lenzilumab in COVID-19

- The Phase 3 results from the LIVE-AIR study were announced, demonstrating that lenzilumab improves survival without the need for mechanical ventilation in hospitalized, hypoxic patients with COVID-19.

- Results from the LIVE-AIR Phase 3 study were published in MedRxiv, (**https://www.medrxiv.org/content/10.1101/2021.05.01.21256470v1.full.pdf**) showing additional analysis from the trial, including patients treated with remdesivir and/or steroids, and a second analysis which showed patients under 85 years of age with C-reactive protein ("CRP"), a widely-utilized inflammatory marker, less than 150 mg/L, derived the greatest benefit of treatment with lenzilumab.
- With the report of positive top-line results from the LIVE-AIR study in March 2021, the company met the first of two specified milestones under the South Korea license agreement with KPM Tech Co., Ltd. and its affiliate, Telcon RF Pharmaceutical, Inc., and received $6.0 million (or $4.5 million net of withholding taxes and other fees and royalties) in the second quarter of 2021.
- In preparation for potential launch under emergency use authorization ("EUA") and conditional marketing authorization ("CMA"), Humanigen entered into several supply agreements with contract manufacturing organizations ("CMOs") to supply bulk drug, fill/finish, and commercial packaging.

Clinical – CAR-T and Oncology

- The positive data from the Phase 1 study of ifabotuzumab in glioblastoma multiforme was presented at the AACR Annual Meeting 2021.
- The CAR-T Phase 1b study results in diffuse large B-cell lymphoma("DLBCL") with lenzilumab were announced, showing 100% Objective Response Rate ("ORR") and no severe cytokine release syndrome or severe neurotoxicity at the recommended dose.
- With the positive Phase 1b results, the company terminated its clinical collaboration agreement with Kite, a Gilead Company, and announced plans to initiate a Phase 2 study with all commercially available CD19 CAR-T therapies for DLBCL patients.

Corporate

- Dr. Adrian Kilcoyne was appointed to the newly created role of Chief Medical Officer.
- Entered into a loan facility with Hercules Capital which will provide the company up to $80 million of secured debt financing.
- The company launched a public offering of common stock which closed after quarter-end, resulting in net proceeds to Humanigen of $94.1 million.
- Two patents were issued for the use of lenzilumab, expanding the company's anti-GM-CSF patent portfolio.

Lenzilumab Regulatory Update

The company recently held a meeting with FDA to discuss the filing of an EUA for lenzilumab for hospitalized, hypoxic COVID-19 patients, where topline data from the LIVE-AIR study were reviewed, along with the timeline for submission of additional clinical and manufacturing data for lenzilumab. The company plans to submit an EUA application at the end of May 2021. The company has also been in discussion with the Medicines and Healthcare Products Regulatory Agency ("MHRA") for the use of lenzilumab in COVID-19 patients in the United Kingdom and

plans to initiate a rolling CMA submission before the end of the second quarter of 2021. The company also plans to submit for CMA to the European Medicines Agency ("EMA") for the use of lenzilumab in the European Union. Further, the company is reviewing the possibility of similar submissions for approval or compassionate use in other territories or countries worldwide.

The company intends to submit a Biologics License Application ("BLA") to FDA in 2022, for the use of lenzilumab in hospitalized, hypoxic COVID-19 patients. Since BLAs typically require more than one study, the company is currently evaluating the extent to which ACTIV-5/BET-B may serve as a basis for a BLA-confirmatory study for lenzilumab.

First Quarter Ended March 31, 2021 Financial Results

Net loss for the three months ended March 31, 2021 was $65.6 million or $1.25 per share as compared to $2.5 million or $0.11 per share for the three months ended March 31, 2020. The increase in net loss for the first quarter 2021 as compared to the first quarter 2020 was largely due to an increase in total expenses, mainly Research and Development expense ("R&D") of $59.2 million from $0.7 million for the three months ended March 31, 2020 to $59.9 million for the three months ended March 31, 2021. The increase in R&D is primarily due to an increase of $51.4 million of expense in lenzilumab manufacturing costs and $7.5 million for clinical trial expenses related to the LIVE-AIR study, both of which began after the first quarter of 2020. The costs incurred for the production of lenzilumab will continue to be included in R&D until lenzilumab is authorized or approved for commercial use, at which point the amounts expended for production will be classified as inventory.

Cash and Cash Equivalents

Net cash used in operating activities, net of balance sheet changes, was $35.8 million for the three months ended March 31, 2021. During the three months ended March 31, 2021, the company raised net proceeds of $36.1 million from the sale of shares of common stock under its At-the-Market offering program. The company drew the first tranche of $25.0 million under its credit facility with Hercules Capital, providing net proceeds of $24.4 million. As of March 31, 2021, the company had cash and cash equivalents of $92.9 million. The company also completed a public offering in the second quarter of 2021 with net proceeds of $94.1 million. The proforma balance of cash and cash equivalents at March 31, 2021 with the proceeds from the public offering is $187.0 million. The company expects to continue to use its funds on development and manufacturing of lenzilumab in anticipation of its potential commercialization under EUA or other conditional marketing authorizations. In the second quarter of 2021 the company anticipates the amount of spending on lenzilumab production will be at least the same level as the first quarter of 2021. If an EUA or CMA for lenzilumab is not received by mid-2021, the company will seek to decrease or eliminate spending on the production of lenzilumab for commercial use.

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

	Three Months Ended March 31,	
	2021	2020
License revenue	$ 486	$ -
Research and development	59,934	659
General and administrative	4,948	1,398
Loss from operations	(64,396)	(2,057)
Net loss	$ (65,567)	$ (2,467)
Net loss per common share	$ (1.25)	$ (0.11)
Weighted average common shares	52,655,756	22,854,106

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 92,892	$ 67,737
Current assets	$ 98,758	$ 68,212
Current liabilities	53,255	20,415
Working Capital	$ 45,503	$ 47,797

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 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). 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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