Humanigen

NEWS RELEASE

UK's MHRA accepts Humanigen's submission of Lenzilumab for Marketing Authorization in COVID-19 for expedited rolling review

7/9/2021

BURLINGAME, Calif.--(BUSINESS WIRE)-- Humanigen, Inc. (Nasdaq: HGEN) ("Humanigen"), today announced its submission for Marketing Authorization for lenzilumab in COVID-19, begun in June 2021, has been accepted by the United Kingdom's (UK's) Medicines and Healthcare Products Regulatory Agency (MHRA) for expedited COVID-related rolling review, with assessment expected to occur more rapidly than a standard rolling review.

Leading up to initiating its submission for Marketing Authorization last month, Humanigen held meetings with various authorities in the UK, including a Rapid C-19 multiagency meeting with representatives from the MHRA, the Therapeutics TaskForce, (TTF), the Department of Health and Social Care (DHSC), National Health Service England (NHSE) and the National Institute for Heath and Care Excellence (NICE).

"We are grateful this submission will receive expedited consideration by MHRA," said Cameron Durrant, CEO of Humanigen. "The global spread of variants of concern, such as the Delta variant, highlights the continued need for proven therapies that are variant-agnostic for millions who remain at risk of COVID-19."

According to Public Health England, despite the first dose vaccination rate of 86% across the UK, the current seven-day hospitalization rate was nearly 2,500, representing a 45% increase over the prior period. Deaths from COVID in the UK reached 161 over the last seven days, an increase of more than 40% compared to the prior seven-day period.1

"We continue to work with our partners to prepare for distribution of lenzilumab pending conditional approval of its use to treat hospitalized patients with COVID-19," noted Timothy E. Morris, COO and CFO of Humanigen. "In the event Emergency Use Authorization in the United States and Marketing Authorization in the UK are awarded concurrently or in parallel, we will work with the relevant authorities to ensure appropriate allocation of lenzilumab in each country."

About Humanigen, Inc.

Humanigen, Inc. (Nasdaq: HGEN) ("Humanigen"), 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 of 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 consequences of a full-blown cytokine storm in hospitalized patients with COVID-19. Humanigen is developing lenzilumab as a treatment for cytokine storm associated with CD19-targeted CAR-T cell therapies and exploring the effectiveness of lenzilumab in other inflammatory conditions such as acute Graft versus Host Disease (GvHD) in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT), eosinophilic asthma, and rheumatoid arthritis. Humanigen is also developing a portfolio of clinical and pre-clinical therapies for the treatment of inflammation and immuno-oncology. For more information, visit **www.humanigen.com** and follow Humanigen on LinkedIn, Twitter, and Facebook.

Humanigen 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 review of our submission for Marketing Authorization for lenzilumab in COVID-19 by the MHRA; our intentions to manage distribution of lenzilumab upon potential receipt of Emergency Use Authorization in the US and Marketing Authorization in the UK; and our other plans to explore the effectiveness of lenzilumab and other candidates in our 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 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 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 of our latest annual and quarterly reports and other filings with the SEC.

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. We undertake 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.

1. **https://coronavirus.data.gov.uk/** accessed July 7, 2020

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