



CalciMedica Announces Positive Topline Data from Interim Analysis of Trial Evaluating Auxora™ in Patients with Severe COVID-19 Pneumonia

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- *Interim results showed Auxora plus standard of care improved time to recovery and reduced ventilator use in patients compared to standard of care alone*

LA JOLLA, Calif., May 28, 2020 – CalciMedica Inc. (“CalciMedica” or the “Company”), a clinical-stage biotechnology company targeting calcium release-activated calcium (CRAC) channels for the treatment of acute and severe inflammatory diseases, today announced positive topline data from an interim analysis of its open-label randomized controlled clinical study of Auxora™ (formerly called CM4620-IE) in patients with severe COVID-19 pneumonia on low-flow oxygen therapy. The interim analysis showed Auxora plus standard of care reduced ventilator use and improved time to recovery in treated patients compared to standard of care alone. Auxora is a potent and selective small molecule CRAC channel inhibitor that prevents CRAC channel overactivation, which can cause pulmonary endothelial damage and cytokine storm in patients with COVID-19.

The open-label study consists of 26 patients enrolled while on low-flow oxygen and randomized 2:1 to receive Auxora versus standard of care. The interim analysis showed that treated patients had a greater than 50% reduction in the proportion of patients put on ventilators in the course of therapy as compared to standard of care patients. Additionally, the length of hospital stay for Auxora treated patients was more than 50% shorter than for standard of care patients. As was announced last week, the FDA has strongly recommended that CalciMedica move into a blinded placebo-controlled study to assess the efficacy of Auxora in treating severe COVID-19 pneumonia.

“I am encouraged by the results of the interim analysis, including the reduction in mechanical ventilation use in patients treated with Auxora,” said Charles A. Bruen, M.D., a critical care and emergency physician at Regions Hospital in St. Paul, Minnesota. “To optimally care for patients with severe COVID-19 disease, it will be essential to introduce a fast-acting therapy that will reduce respiratory complications as part of the standard of care.”

Joseph Miller, M.D., a Henry Ford Hospital emergency medicine physician and a principal investigator in the trial added, “The clinical outcomes from this study demonstrate the potential effectiveness of Auxora for treating severe pneumonia in COVID-19 patients. We look forward to further investigating this therapy in future research.”

The U.S Food and Drug Administration (FDA) has strongly recommended that CalciMedica transition from the current randomized open-label study to a blinded placebo-controlled trial as soon as possible. The open-label randomized controlled clinical study enrolled one study arm in patients with severe COVID-19 pneumonia on low-flow oxygen therapy and an additional second study arm in patients with critical COVID-19 pneumonia on high-flow oxygen therapy. Following the recommendation from the FDA, the severe arm of the study is shifting to a blinded, placebo-controlled design, with patients randomized 1:1 to receive Auxora plus standard of care or standard of care alone. CalciMedica is planning to submit the results of the low-flow oxygen therapy arm to a peer-reviewed publication. Regions Hospital in St. Paul, Minnesota, Henry Ford Hospital in Detroit and additional sites across the U.S have been dosing severe and critical COVID-19 pneumonia patients with Auxora under an Investigational New Drug program (IND).

For more details on the clinical study, visit clinicaltrials.gov.

About Auxora™ (formerly CM4620-IE)

Auxora is a potent and selective small molecule inhibitor of CRAC channels. CRAC channels are found on many cell types, including lung endothelium cells, pancreatic acinar cells and immune system cells, where aberrant activation of these channels may play a key role in the pathobiology of acute and chronic inflammatory syndromes. Auxora is an investigational drug being developed for use in patients with COVID-19 pneumonia and for use in patients with acute pancreatitis and accompanying SIRS. In addition, CalciMedica is exploring other acute indications for Auxora such as viral pneumonia, acute lung injury, ARDS and acute kidney injury.

About CalciMedica, Inc.

CalciMedica is a privately-held, clinical stage biotechnology company focused on CRAC channel drug discovery and development for the treatment of acute and chronic inflammatory diseases. CRAC channels control the entry of calcium into immune and other cell types, and calcium is an important intracellular signaling molecule that modulates normal cellular function but can be detrimental when levels are too high. CalciMedica is headquartered in San Diego, CA. For more information, please visit the company website at www.calcimedica.com.

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