



CalciMedica Announces that FDA Has Strongly Recommended Moving to a Blinded Placebo-controlled Trial with Auxora™ in Patients with Severe COVID-19 Pneumonia

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LA JOLLA, Calif., May 21, 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 that it has received guidance from the U.S. Food and Drug Administration (FDA) regarding the Company's ongoing study of Auxora™ (formerly called CM4620-IE) in patients with COVID-19 pneumonia. The 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 FDA provided this recommendation following the submission of a recent interim analysis of Auxora in patients suffering from severe COVID-19 pneumonia. The interim analysis was conducted by CalciMedica following an Independent Safety Review Committee (ISRC) recommendation to continue the study.

"We are encouraged by the FDA's recommendation to transition our ongoing study to a blinded, placebo-controlled trial," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "As many patients with COVID-19 pneumonia continue to fight for their lives with limited treatment options, we are committed to developing a potential therapy to reduce systemic inflammation and respiratory complications that may require ventilator use. The ISRC recommended that we continue enrollment in our study following the interim safety checkpoint built into the trial design. We believe the FDA's subsequent guidance highlights the potential for Auxora to improve patient outcomes, enable them to leave the hospital sooner, and reduce the burden of COVID-19 on healthcare providers."

Auxora is a potent and selective small molecule CRAC channel inhibitor that prevents CRAC channel overactivation. It has been shown that CRAC channel overactivation can cause pulmonary endothelial damage and cytokine storm in COVID-19. The ongoing open-label randomized controlled clinical study aims to evaluate 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 expected to shift to a blinded, placebo-controlled design, with patients randomized 1:1 to receive Auxora plus standard of care or standard of care alone. 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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