



CalciMedica

CalciMedica Expands Clinical Study to Assess CM4620-IE in Patients with Critical COVID-19 Pneumonia on High-Flow Oxygen Therapy

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- *Phase 2 open-label study expands to additional sites across the U.S. and aims to enroll 120 patients*

LA JOLLA, Calif., April 30, 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 the addition of a study arm to investigate the use of CM4620-IE in patients with critical COVID-19 pneumonia on high-flow nasal cannula oxygen therapy, in which high levels of oxygen are delivered into the lungs of patients through the nose. CM4620-IE 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 COVID-19. The compound has demonstrated clinical safety and potential efficacy in patients with hypoxemia secondary to systemic inflammatory response syndrome (SIRS) from acute pancreatitis.

“As we gain a better understanding of COVID-19, and treatment protocols shift to less-invasive therapies such as high-flow nasal cannula oxygenation rather than mechanical ventilators, our goal is to continue to provide a therapy with potential to stabilize the patient, reduce systemic inflammation and prevent further respiratory complications” said Sudarshan Hebbar, M.D., chief medical officer of CalciMedica. “This additional study arm gives us the opportunity to treat patients with COVID-19 pneumonia at a more advanced stage of lung dysfunction using our fast-acting agent, CM4620-IE.”

CalciMedica recently received a “Study May Proceed” letter from the U.S. Food and Drug Administration (FDA), allowing the Company to investigate the use of CM4620-IE in patients with severe COVID-19 pneumonia at risk for progression to acute respiratory distress syndrome (ARDS). The open-label Phase 2 clinical study aims to enroll a total of 120 patients with COVID-19 pneumonia. The initial study arm in severe patients on low-flow oxygen therapy has commenced and aims to enroll 40 patients randomized to receive CM4620-IE plus standard of care and 20 randomized to receive standard of care alone. The additional study arm in critical patients on high-flow oxygen therapy also aims to enroll 40 patients randomized to receive CM4620-IE and 20 randomized to receive standard of care alone. Patients receiving high flow oxygen therapy are differentiated from patients receiving low flow oxygen therapy as they are considered critical rather than severe by the FDA. 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 CM4620-IE under this IND.

When a patient is infected with SARS-CoV-2, host immune responses can lead to cytokine storm, which in turn causes severe pneumonia and hypoxemic respiratory failure, ARDS, death or in the case of survivors, permanently compromised pulmonary function. According to the World Health Organization, as of April 29, 2020, there were 3,173,036 confirmed cases and 225,927 deaths due COVID-19 globally.

About CM4620

CM4620 is a potent and selective small molecule inhibitor of CRAC channels. CRAC channels are found on many cell types, including immune cells, where aberrant activation of these channels may play a key role in the pathobiology of acute and chronic inflammatory syndromes. CalciMedica’s proprietary CM4620 is being developed for patients with acute pancreatitis and accompanying SIRS and for patients with severe COVID-19 pneumonia.

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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