



FDA Grants CalciMedica Permission to Begin Dosing CM4620-IE in Patients with Severe COVID-19 Pneumonia under a Newly Opened IND

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- *Regions Hospital in St. Paul, Minnesota has begun a Phase 2 clinical study of CM4620-IE in patients with severe COVID-19 pneumonia this week, and Henry Ford Hospital in Detroit is expected to begin the trial within the next week*
- *CM4620-IE is a potent and selective small molecule that may prevent pulmonary endothelial damage and lessen the cytokine storm in COVID-19*
- *CM4620-IE has demonstrated clinical safety and potential efficacy in patients with hypoxemia secondary to systemic inflammatory response syndrome in the setting of acute pancreatitis*

LA JOLLA, Calif., April 9, 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 it has received a "Study May Proceed" letter from the U.S. Food and Drug Administration (FDA) to investigate the use of CM4620-IE in patients with severe COVID-19 pneumonia who are at risk for progression to acute respiratory distress syndrome (ARDS). 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. It has demonstrated clinical safety and potential efficacy in patients with hypoxemia secondary to systemic inflammatory response syndrome (SIRS) from acute pancreatitis.

"There is a dire need for a fast-acting, potent treatment for patients with severe COVID-19 pneumonia," said Charles A. Bruen, M.D., a critical care and emergency physician at Regions Hospital in St. Paul, Minnesota. "Recent clinical studies demonstrated safety and potential efficacy of CM4620-IE in critically ill patients with acute pancreatitis. Its rapid onset makes it ideal for acute settings. It has the potential to prevent the development of ARDS in patients with severe COVID-19 pneumonia and reduce the need for ventilators at a time when there is a shortage of ventilators in healthcare facilities across the U.S."

CalciMedica's rapid receipt of notification from the FDA that it could proceed with its study is part of the agency's initiative to expedite access to investigational drugs for the treatment COVID-19. The open-label Phase 2 clinical study aims to enroll 60 patients with severe COVID-19 pneumonia. Forty patients will be assigned to receive CM4620-IE plus standard of care and 20 assigned to receive standard of care alone. The first patients are being enrolled at Regions Hospital in St. Paul and additional patients are expected to be enrolled within the next week at Henry Ford Hospital in Detroit. Additional study sites are being evaluated.

Sudarshan Hebbar, M.D., chief medical officer of CalciMedica, added, "The FDA's quick decision to allow CalciMedica to proceed with dosing of COVID-19 patients underscores the potential of CM4620-IE to benefit these patients. Patient safety is key for us as we rapidly evaluate CM4620-IE in patients with severe COVID-19 pneumonia. Due to the fast-acting nature of the drug, it may quickly lessen the cytokine storm associated with COVID-19 and may stabilize the pulmonary endothelial capillary barrier and prevent more serious lung injury."

For patients infected with SARS-CoV-2, morbidity and mortality can arise from host immune responses. These 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 8, 2020, there were 1,353,361 confirmed cases and 79,235 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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