



CalciMedica Announces Independent Safety Review Committee Recommendation to Continue Phase 2 Study of CM4620-IE in Patients with Severe COVID-19 Pneumonia on Low-Flow Oxygen Therapy

May 7, 2020 11:00 AM EDT

LA JOLLA, Calif., May 7, 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 the Independent Safety Review Committee (ISRC) recommended that its open-label Phase 2 study evaluating the safety, efficacy and pharmacokinetic profile of CM4620-IE in patients with severe COVID-19 pneumonia continue as planned. The ISRC reviewed available data to assess the risk/benefit to patients on drug and recommended that the trial continue without modification.

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 open-label randomized controlled Phase 2 clinical study aims to enroll a total of 120 patients with COVID-19 pneumonia on oxygen therapy. 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 patients 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 patients 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 U.S Food and Drug Administration. 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.

For more details on the clinical study, go to clinicaltrials.gov.

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.

CalciMedica Contact:

Rachel Leheny, Ph.D.
Chairman and Chief Executive Officer
rachel@calcimedica.com
858-952-5500

Media Contact:

Karen O'Shea, Ph.D.
LifeSci Communications
koshea@lifescicomms.com
929-469-3860