



CalciMedica Announces IDMC Recommendation to Continue with Trial Evaluating Auxora™ in Patients with Severe COVID-19 Pneumonia

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LA JOLLA, Calif., December 17, 2020 – CalciMedica Inc. (“CalciMedica” or the “Company”), a clinical-stage biotechnology company targeting calcium release-activated calcium (“CRAC”) channels for the treatment of severe acute and chronic inflammatory diseases, today announced that the trial evaluating Auxora™ in patients with severe COVID-19 pneumonia has received a recommendation to continue, following a pre-scheduled safety review by an Independent Data Monitoring Committee (IDMC). The IDMC recommendation that the trial continue is based on an unblinded analysis of safety data from over 50 patients. The company expects to have more than 100 patients enrolled by the end of December.

“We are encouraged by the IDMC recommendation to continue evaluating Auxora in patients with severe COVID-19, especially at this critical time when hospitalizations are rapidly rising and communities across the country continue to struggle to contain the pandemic,” said Sudarshan Hebbar, M.D., chief medical officer of CalciMedica. “We remain on track to finish our COVID-19 pneumonia study by April of 2021. We continue to look at other uses for our drug in which Auxora will beneficially reduce systemic inflammation and prevent respiratory failure requiring ventilator use, including in acute pancreatitis with accompanying systemic inflammatory response syndrome (SIRS), where we plan to start enrolling a Phase 2b trial in the first quarter of 2021.”

Auxora is a potent and selective small molecule CRAC channel inhibitor that prevents CRAC channel overactivation. In results published in [Critical Care](#), Auxora combined with standard of care therapy showed faster recovery and reduced use of invasive mechanical ventilation and death in patients with severe COVID-19 pneumonia, as compared to standard of care alone. In May 2020, the FDA strongly recommended CalciMedica move to a blinded placebo-controlled trial with Auxora in patients with severe COVID-19 pneumonia.

The ongoing blinded, placebo-controlled clinical trial is enrolling up to 400 patients with severe COVID-19 pneumonia to assess Auxora plus standard of care compared to placebo plus standard of care alone. Patients will receive either Auxora or matched lipid nano-emulsion placebo in addition to standard of care, which may include both remdesivir and dexamethasone. Up to 40 sites across the United States are expected to enroll patients. For more information about the clinical trial, visit clinicaltrials.gov.

About Auxora™ (formerly CM4620-IE)

CalciMedica's lead clinical compound, Auxora, is a potent and selective small molecule inhibitor of Orai1-containing CRAC channels that is being developed for use in patients with severe COVID-19 pneumonia and in patients with acute pancreatitis and accompanying systemic inflammatory response syndrome. 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. CalciMedica is also exploring other acute indications for Auxora such as viral pneumonia, acute lung injury, acute respiratory distress syndrome and acute kidney injury.

About CalciMedica, Inc.

CalciMedica is a privately held, clinical-stage biotechnology company with a platform focused on CRAC channel drug discovery and development for the treatment of severe acute and chronic inflammatory diseases, including acute pancreatitis, chronic pancreatitis, COVID-19 pneumonia and acute respiratory distress syndrome (ARDS). The company has a portfolio of potent and selective small molecule CRAC channel inhibitors, including its lead product Auxora, that prevent CRAC channel overactivation that can cause organ injury including endothelial apoptosis, pancreatic necrosis, tissue fibrosis and diffuse alveolar damage in numerous settings. Data from both a Phase 2a acute pancreatitis trial and a Phase 2 COVID-19 pneumonia trial suggest that Auxora prevents organ tissue damage and allows for organ function. CalciMedica is headquartered in San Diego, CA. For more information, please visit the company website at www.calcimedica.com.

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