



CalciMedica Initiates CARDEA-Plus: A Clinical Trial of Auxora™ in Patients with Critical COVID-19 Pneumonia

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CARDEA-Plus is designed to evaluate dosing, safety and efficacy of Auxora in combination with both tocilizumab and corticosteroids

LA JOLLA, Calif., January 20, 2022 – CalciMedica Inc. (CalciMedica or the Company), the CRAC (calcium release-activated calcium) channel company, today announced the initiation of CARDEA-Plus, a Phase 2b clinical trial being conducted in the United States and Canada, that may serve as a lead-in to its Phase 3 development program of Auxora™ in patients with critical COVID-19 pneumonia. The trial is designed to accumulate additional patient safety data with Auxora, assess the safety and efficacy of Auxora in combination with both tocilizumab and corticosteroids, and assess the safety and efficacy of three versus six days of dosing. The Company recently reported topline data from its CARDEA Phase 2 trial that support further studies in this patient population.

CARDEA-Plus will enroll COVID-19 pneumonia patients with a PaO₂/FiO₂ (P/F) ratio of ≤200 who require high-flow nasal cannula (HFNC) or noninvasive ventilation (NIV). Patients will receive a 2.0 mg/kg initial dose of Auxora followed by 1.6 mg/kg at 24 hours, and 1.6 mg/kg at 48 hours. Those patients with either a P/F ratio of ≤100 or on mechanical ventilation at 48 hours will be eligible to be randomized to receive either three doses of Auxora or three doses of placebo. All patients will receive standard of care which may include the use of corticosteroids and/or tocilizumab.

“Despite increasing vaccination rates for COVID-19, the high number of hospitalizations and deaths still pose a significant problem,” said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. “While tocilizumab has become widely used in patients hospitalized with COVID-19, there continues to be a need to improve patient outcomes. We believe Auxora has a unique mechanism of action and pharmacokinetic properties that may provide clinical benefit to patients with critical COVID-19 pneumonia.”

“The initiation of this study, which also allows for administration of Auxora with tocilizumab and corticosteroids in patients with critical COVID-19 pneumonia, is a significant milestone for our Company,” said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. “Importantly, the results of this study, to be followed by discussions with the FDA, will inform the design of a potential Phase 3 clinical trial later this year. We have received broad enthusiasm and support from investigator sites for this study and anticipate rapid enrollment.”

About Auxora

CalciMedica’s lead product candidate is Auxora, a potent and selective intravenous (IV) formulated small molecule CRAC channel inhibitor that in animal models and in clinical trials has prevented acute epithelial and/or endothelial cell injury and inflammation in organs, such as the pancreas, lungs and kidneys. Auxora is currently being evaluated in multiple ongoing clinical trials: a blinded, placebo-controlled Phase 2b trial in patients with acute pancreatitis with accompanying systemic inflammatory response syndrome (SIRS), a Phase 2 dose-escalation trial in patients with COVID-19 pneumonia and acute respiratory distress syndrome (ARDS) requiring invasive mechanical ventilation, and an investigator-initiated Phase 1/2 trial in pediatric acute lymphocytic leukemia (ALL) patients who develop acute pancreatitis as a result of a specific chemotherapy. Auxora has been evaluated in CARDEA, a 284-patient randomized, placebo-controlled trial in hospitalized COVID-19 pneumonia patients that was Part Two of a Phase 2 study. Results of Part One of the Phase 2 study, a randomized open label trial in 30 critical and severe COVID-19 pneumonia patients, were published in the peer reviewed journal, *Critical Care*, in August 2020. Results of a randomized open label Phase 2a trial in 21 acute pancreatitis patients with SIRS were published in the peer reviewed journal, *Pancreas*, in June 2021.

About CalciMedica, Inc.

CalciMedica is a clinical-stage biopharmaceutical company advancing a new class of medicines designed to act upon calcium release-activated calcium (CRAC) channels, a group of ion channel targets not addressed by any approved drugs. CalciMedica is developing CRAC channel inhibitors for unmet needs in acute critical illness and looks to expand the potential uses of CRAC channel inhibitors to certain chronic diseases that have the common thread of inflammation in their pathogenesis. The Company has a portfolio of potent and selective small molecule CRAC channel inhibitors including Auxora, its lead product candidate, which is formulated as a proprietary IV nanoemulsion specifically designed for acute critical illnesses.

CalciMedica is headquartered in La Jolla, CA. For more information, please visit the company website at www.calcimedica.com.

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