



## CalciMedica Announces Publication of Results from CARDEA COVID-19 Study in Critical Care

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– Results further support therapeutic potential of Auxora in respiratory diseases and other inflammatory diseases –

LA JOLLA, Calif., April 14, 2022 – CalciMedica Inc. (CalciMedica or the Company), the CRAC (calcium release-activated calcium) channel company, today announced the publication of results from the Company's CARDEA clinical trial, a Phase 2 trial of Auxora in severe COVID-19 pneumonia, in *Critical Care*, a peer-reviewed, international medical journal. The article, titled "[Auxora vs. placebo for the treatment of patients with severe COVID-19 pneumonia: a randomized-controlled clinical trial](#)," details the trial findings on Auxora, CalciMedica's lead CRAC channel inhibitor product candidate.

"Auxora was noted to hasten recovery, reduce mortality, and was well-tolerated in patients hospitalized with COVID-19 pneumonia and moderate to severe hypoxemic respiratory failure," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "These findings provide support for the continued development of Auxora and suggest that Auxora may potentially have therapeutic benefit for respiratory failure due to other causes in addition to COVID-19 pneumonia."

CARDEA is a Phase 2, randomized, double-blind, placebo-controlled trial evaluating the addition of Auxora to corticosteroids and standard of care in adults with severe COVID-19 pneumonia. Eligible patients were adults with more than one symptom consistent with COVID-19 infection, a diagnosis of COVID-19 confirmed by laboratory testing using polymerase chain reaction or other assay, and pneumonia documented by chest imaging. Patients were also required to be receiving oxygen therapy using either a high flow or low flow nasal cannula at the time of enrollment and, for the 261 patients in the analysis set, to have at the time of enrollment, a baseline imputed PaO<sub>2</sub>/FiO<sub>2</sub> ratio > 75 and ≤ 200. The PaO<sub>2</sub>/FiO<sub>2</sub> was imputed from a SpO<sub>2</sub>/FiO<sub>2</sub> determined by pulse oximetry using a non-linear equation. Patients could not be receiving either non-invasive or invasive mechanical ventilation at the time of enrollment. The primary endpoint was time to recovery through Day 60, with secondary endpoints of all-cause mortality at Day 30 and Day 60.

The major findings of the Phase 2 trial as reported in *Critical Care* are as follows:

- Time to recovery was seven vs. ten days (P = 0.0979) for patients who received Auxora vs. placebo, respectively.
- Day 30 all-cause mortality was 7.7% with Auxora vs. 17.6%, with placebo (P = 0.0165).
- Day 60 all-cause mortality was 13.8% with Auxora vs. 20.6% with placebo (P = 0.1449).
- Serious adverse events occurred in 24.1% of patients treated with Auxora vs. 35% of patients receiving Placebo (P=0.0616).

"These data demonstrate Auxora's potential to address severe and critical COVID-19 and potentially further our ability to treat the disease using an alternative mechanism of action, while also advancing our knowledge of the use of Auxora in respiratory diseases more generally," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "We are encouraged by the findings as they support the potency and versatility of Auxora in respiratory diseases as well as in other inflammatory diseases. We look forward to sharing clinical updates on Auxora from other trials throughout this year and next."

Auxora is being evaluated in multiple indications, including acute pancreatitis with accompanying systemic inflammatory response syndrome, and acute kidney injury. The CARDEA-Plus follow-up trial to CARDEA in COVID-19 pneumonia patients was recently halted, prior to enrolling any patients, due to declining COVID-19 cases and re-evaluation of the optimal clinical path forward for Auxora in COVID-19 pneumonia. The Company is focusing on its Auxora clinical programs in acute pancreatitis and acute kidney injury while assessing opportunities to study Auxora in respiratory failure and acute respiratory distress syndrome (ARDS) due to all viral pneumonia, including COVID-19 pneumonia, based on the CARDEA results.

To view the online publication, click [here](#).

### 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 trial. Results of Part One of the Phase 2 trial, 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](http://www.calcimedica.com).

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