



CalciMedica Announces Data Showing Auxora™ Substantially Improved Outcomes in Patients with Severe COVID-19 Pneumonia

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- *Median time to recovery was more than two times faster for patients treated with Auxora plus standard of care compared to standard of care alone*
- *The percentage of patients requiring invasive mechanical ventilation was 2.8 times lower with Auxora plus standard of care compared to standard of care alone*
- *Treating 2.6 patients with Auxora prevented one intubation or death over 30 days*
- *CalciMedica plans to initiate a 400-patient, blinded placebo-controlled efficacy study of Auxora plus standard of care vs. placebo plus standard of care, which may include dexamethasone and remdesivir*

LA JOLLA, Calif., July 16, 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 data from a randomized, controlled, open-label clinical study showing substantially improved outcomes with Auxora™ (formerly called CM4620-IE) as a treatment for severe COVID-19 pneumonia. Auxora, a potent and selective small molecule CRAC channel inhibitor, combined with standard of care therapy improved outcomes in patients with severe COVID-19 pneumonia showing faster recovery and reduced use of invasive mechanical ventilation and death as compared to standard of care alone. Auxora also demonstrated a favorable safety profile in patients with both severe and critical COVID-19 pneumonia compared to standard of care alone. The manuscript by lead authors Charles Bruen, M.D. and Joseph Miller, M.D. describing the clinical data titled “*Auxora versus Standard of Care for the Treatment of Severe or Critical COVID-19 Pneumonia: Results from a Randomized Controlled Trial*” is available on an online preprint server at <https://www.researchsquare.com/article/rs-42600/v1>.

“As the number of COVID-19 cases rise across the U.S., there is an urgent need for a safe, fast-acting therapy like Auxora to address COVID-19 associated respiratory complications as part of the standard of care,” said Charles Bruen, M.D., a critical care and emergency physician at Regions Hospital in St. Paul, Minnesota. “We are encouraged by the data because it further supports Auxora’s potential to improve outcomes in patients suffering from severe COVID-19 pneumonia, which is critical for a condition that too often proves to be life-threatening despite improvements in treatment options.”

Joseph Miller, M.D., a Henry Ford Hospital emergency medicine physician and a principal investigator in the trial added, “The clinical outcomes from this study demonstrate the potential effectiveness of Auxora for treating severe pneumonia in COVID-19 patients. We look forward to further investigating this therapy in future research.”

Sudarshan Hebbar, M.D., chief medical officer of CalciMedica, added, “The years of research we have put into determining the optimal delivery of Auxora is translating into marked clinical improvement for patients. As a potent CRAC channel inhibitor formulated in a lipid nano-emulsion, Auxora has the ability to go rapidly to the lung and protect against the pulmonary damage observed in COVID-19 patients. We believe Auxora protects the lung endothelium, preserving its barrier function and facilitating oxygenation. The results in this article support our plans to move to a randomized, blinded, placebo-controlled study of Auxora as recommended by the FDA.”

The primary objectives of the study were to assess the safety and tolerability of Auxora, changes in clinical status based on an 8-point ordinal scale, and the proportion of patients dying or requiring invasive mechanical ventilation in the 30 days after randomization. Patients were randomized 2:1 to receive three doses of once-daily Auxora plus standard of care versus standard of care alone. Seventeen patients with severe COVID-19 pneumonia (receiving low flow supplemental oxygen therapy) were randomized to Auxora plus standard of care, while nine patients were randomized to standard of care alone. In addition, three patients with critical COVID-19 pneumonia (receiving high flow supplemental oxygen therapy) were randomized to receive Auxora plus standard of care while one received standard of care alone. Efficacy analyses were conducted on the 26-patient severe cohort while safety analyses were conducted on the 30-patient combined severe and critical cohort.

A comparison of efficacy outcomes between patients with severe COVID-19 pneumonia treated with Auxora plus standard of care and those treated with standard of care alone revealed:

- Median time to recovery with Auxora plus standard of care was five days versus 12 days with standard of care alone.
- Invasive mechanical ventilation was needed in 18% of patients receiving Auxora plus standard of care versus 50% receiving standard of care alone (absolute risk reduction=32%; 95% CI, -0.07 to 0.71).
- One intubation or death over 30 days would be prevented by the treatment of 2.6 patients with Auxora.

- Outcomes measured by an 8-point ordinal scale were significantly improved for patients receiving Auxora, especially for patients with a baseline imputed $\text{PaO}_2/\text{FiO}_2$ of 101-200.

Safety analyses revealed that the proportion of patients receiving Auxora experiencing ≥ 1 adverse event was similar to those receiving standard of care (75% versus 80%, respectively). Fewer patients receiving Auxora experienced serious adverse events when compared with standard of care alone (30% versus 50%, respectively). There were no drug-related serious adverse events observed.

CalciMedica plans to begin Part 2 of this clinical trial in the coming weeks and has recently received FDA clearance of its protocol for this blinded, placebo-controlled stage of the study. Up to 400 patients will be randomized 1:1 to receive either Auxora or matched lipid nano-emulsion in addition to standard of care which may include both remdesivir and dexamethasone. Patients with $100 < \text{PaO}_2/\text{FiO}_2 < 300$ will be included and the number of patients with $\text{PaO}_2/\text{FiO}_2 > 200$ will be capped in order to enrich for sicker patients whom the Company believes will have the greatest benefit from Auxora. Time to recovery based on the 8-point ordinal scale will be the primary endpoint and a composite of ventilator use and death will be a secondary endpoint.

For more details on the upcoming study please visit clinicaltrials.gov.

As the manuscript is currently under peer review at a medical journal, the findings are provisional and the conclusions may change once peer review is complete. The manuscript was published on the preprint server per guidelines to ensure that research findings and data relevant to the novel coronavirus pandemic are shared rapidly and openly.

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 (SIRS). 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 (ALI), acute respiratory distress syndrome (ARDS) and acute kidney injury (AKI).

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 acute and severe inflammatory diseases. The Company was founded in 2007 by Ken Stauderman, CalciMedica's Chief Scientific Officer, and colleagues at Torrey Pines Therapeutics in San Diego and Harvard's Center for Blood Research in Cambridge, MA. Dr. Stauderman's work includes the discovery of the role of STIM1, which works in concert with Orai1 in the CRAC channels targeted by CalciMedica's drugs. The Company has a portfolio of highly selective CRAC channel inhibitor drugs that it is developing to improve outcomes for patients with acute inflammatory indications. It has also assembled a portfolio of patents and patent applications covering those compounds as well as different aspects of CRAC channel biology. 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