CalciMedica Publishes Positive Data from Phase 2a Study of Auxora in Patients with Acute Pancreatitis and Announces First Patients Dosed in Phase 2b Study

June 2, 2021 11:00 AM EDT

Data from Phase 2a Study Demonstrated Patients Treated with Auxora Experienced Reduced Severity of Acute Pancreatitis, Less Persistent Systemic Inflammatory Response Syndrome (SIRS) and More Rapid Restoration of Gut Function with Favorable Safety Profile

Patient dosing has begun in Phase 2b study in acute pancreatitis; data expected H2 2022

LA JOLLA, Calif., June 2, 2021 – CalciMedica Inc. ("CalciMedica" or the "Company), a clinical-stage biotechnology platform company targeting calcium release-activated calcium (CRAC) channels for the treatment of severe acute and chronic inflammatory diseases, today announced the publication of results from the Company's completed randomized, open-label, dose-response Phase 2a study in the peer-reviewed journal *Pancreas*, part of the ongoing Phase 2 program of Auxora, a potent and selective small molecule inhibitor of Orai1-containing calcium release-activated calcium (CRAC) channels, in patients with acute pancreatitis with systemic inflammatory response syndrome (SIRS). The research presented in the manuscript, entitled "Auxora for the Treatment of Patients With Acute Pancreatitis and Accompanying Systemic Inflammatory Response Syndrome," was conducted by lead authors Charles Bruen, M.D., and Joseph Miller, M.D.

The study randomized 21 patients with acute pancreatitis, accompanying SIRS and hypoxemia, to receive high- or low-dose Auxora plus standard of care or standard of care alone. The primary objective of the study was to assess patient safety and patient benefit while identifying efficacy endpoints for potential future studies. The published results show that from screening to day 5 or discharge, three patients receiving Auxora experienced improvements in the severity of acute pancreatitis as demonstrated by contrast-enhanced computed tomography (CECT) scans, compared with none in the standard of care group. In addition, fewer patients receiving Auxora experienced persistent SIRS and more experienced rapid restoration of gut function than patients receiving standard of care alone. This allowed for better tolerability of solid foods within 72 hours of treatment and earlier hospital discharge, resulting in reduced median hospital stay in the Auxora treatment groups compared with those receiving standard of care, especially among patients with moderate or severe acute pancreatitis. Efficacy signals were observed across both high-dose and low-dose cohorts. Auxora also demonstrated a favorable safety profile, with the majority of treatment-emergent adverse events (TEAEs) being mild in severity and there was no increase in reported SAEs compared with the standard of care.

"The fast-acting nature of Auxora, which was, on average, administered within 24 hours of onset of symptoms in this study, is of particular importance as it is critical to treat the pancreatic injury and associated inflammatory response from acute pancreatitis quickly to prevent persistent SIRS and organ failure , thereby decreasing the risk of mortality," said Robert Sutton, M.D., MB, BS, DPhil, FRCS, Professor of Surgery at the University of Liverpool and Liverpool University Hospitals NHS Foundation Trust, and chairman of the Steering Committee for the Phase 2b study. "Auxora may be an important, novel therapy for the management of patients with acute pancreatitis and accompanying SIRS. Auxora's demonstrated ability to distribute rapidly to the pancreas and lungs, resulting in a fast onset of action, and achieve effective inhibition of CRAC channels in pancreatic and pulmonary tissue, will offer significant improvement over the current treatment regimen for these patients – still without specific, targeted therapy. The favorable safety profile and rapid improvements in patient outcomes observed with Auxora warrant further clinical development in a larger randomized, double-blind, Phase 2b study, now underway, and I look forward to taking part in that study and sharing results when available."

"Acute pancreatitis is a local and systemic inflammatory disease associated with significant morbidity and mortality, resulting in at least 275,000 hospitalizations per year in the United States and representing a significant area of unmet need," said Rachel Leheny, Ph.D., chief executive officer of CalciMedica. "Because current treatments are inadequate, and since most acute pancreatitis patients visit the ER and many are hospitalized, it places a tremendous burden on patients, their families, and the healthcare system. Recent evidence suggests that calcium influx via CRAC channels is involved in the development of both pancreatic necrosis and systemic inflammation which can result in respiratory failure, and that overactivation of CRAC channels appears to play a significant role in injuring pancreatic cells. Today we are proud to add to this growing body of data by showing that Auxora, a potent and selective small molecule inhibitor of CRAC channels, demonstrated initial signs of efficacy in reducing the severity of acute pancreatitis and lessening the frequency of persistent SIRS among other endpoints. Auxora has now been tested in nearly 200 critically-ill patients across five clinical trials, demonstrating a positive safety profile."

The Company also announced that the first patients have been dosed in a multi-center, randomized, double-blind Phase 2b study of Auxora in patients with acute pancreatitis with SIRS. The Phase 2b study will evaluate three doses of Auxora for tolerability and efficacy and enroll up to 216 patients. Patients will be randomly assigned to either Auxora at one of three dose levels or placebo, and study drug infusions will occur every 24 hours for three consecutive days for a total of three infusions. The primary outcome measure is time to food tolerance, with other measures of drug pharmacology and efficacy as secondary endpoints. Top-level data from the Phase 2b study is expected in the second half of 2022.

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 acute pancreatitis and accompanying systemic inflammatory response syndrome (SIRS) and in patients with COVID-19 pneumonia. CRAC channels are found on many cell types, including pancreatic acinar cells, lung endothelium 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. Auxora is currently being evaluated in a Phase 2b trial for acute pancreatitis with accompanying SIRS, a Phase 2b trial for COVID-19 severe and critical pneumonia patients and a Phase 2 dose escalation study in critical COVID-19 patients. In previous trials patients responded well to Auxora regardless of severity or cause of disease. CalciMedica is also exploring other acute indications for Auxora such as acute lung injury, acute respiratory distress syndrome and acute kidney injury.

About Acute Pancreatitis

Acute Pancreatitis occurs when inflammation of the pancreas develops rapidly due to various causes, with symptoms such as abdominal pain, nausea and vomiting, diarrhea and fever. The condition, for which no disease-modifying therapies are currently available, is typically treated using supportive

care such as IV fluids and pain medication. Leading etiologies are gallstones and alcohol, although hypertriglyceridemia, drug reactions- and trauma- are also commonly observed. According to the National Institute of Diabetes and Digestive and Kidney Diseases, there are about 275,000 hospital stays for acute pancreatitis each year in the U.S.

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 in numerous settings, including endothelial apoptosis, pancreatic necrosis, tissue fibrosis and diffuse alveolar damage. 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 rapid restoration of organ function. CalciMedica is headquartered in San Diego, CA. For more information, please visit the company website at www.calcimedica.com.

CalciMedica Contact:

Argot Partners
calcimedica@argotpartners.com
212.600.1902