CalciMedica Announces First Patient Enrolled in International Expansion of CARPO Trial of Auxora™ in Acute Pancreatitis (AP)

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CARPO top-line data expected in 1H2024

CARPO enrolling in over 30 sites in the US and India

LA JOLLA, Calif., Aug. 09, 2023 (GLOBE NEWSWIRE) -- CalciMedica Inc. ("CalciMedica") (NASDAQ: CALC), a clinical-stage biopharmaceutical company focused on developing novel calcium release-activated calcium (CRAC) channel inhibition therapies for acute and chronic inflammatory and immunologic illnesses, today announced that its ongoing CARPO trial, a Phase 2b trial evaluating Auxora™ for the treatment of acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS), was expanded to clinical research sites in India and that the first patient has been enrolled there.

Overseeing the trial in India as a member of the steering committee is Dr. Pramod Garg, Professor of Gastroenterology and Associate Dean of Research at the All India Institute of Medical Sciences in New Delhi, India.

"We are thrilled to have Dr. Garg overseeing the continuation of our Phase 2b CARPO study in acute pancreatitis in India," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "Further, we are excited that the study sites in India have significant experience in conducting clinical trials for AP and other critical illnesses. As we move forward with CARPO internationally, we hope to build upon the promising data from our Phase 2a trial of Auxora in patients with AP and accompanying SIRS and the trials in patients with severe or critical COVID-19 pneumonia."

CARPO is expected to enroll approximately 216 patients at more than 30 sites in the United States and India. The randomized, double-blind, placebo-controlled, dose-ranging trial is intended to demonstrate the tolerability and potential efficacy of Auxora in patients who have AP with accompanying SIRS, a condition that can be life-threatening and for which there is currently no approved therapy. Data from the CARPO trial are expected in the first half of 2024.

"The expansion of CARPO to include international sites is a meaningful achievement in our mission to help patient populations globally whose needs are currently unmet," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "Auxora is a promising therapeutic candidate that has demonstrated in previous clinical trials its strong potential to address the underlying pathobiology of AP and provide a much-needed therapy for these severely ill patients. We look forward to seeing the results from CARPO in the first half of next year."

About Auxora™
CalciMedica's lead clinical compound, Auxora™, is a potent and selective small molecule inhibitor of Orai1-containing calcium release-activated calcium (CRAC) channels that is being developed for use in patients with inflammatory illnesses. 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: (i) a Phase 2b trial for acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS) called CARPO, (ii) an investigator-sponsored Phase 1/2 trial called CRSPA being conducted in pediatric patients with asparaginase-induced pancreatic toxicity ("AIPT") (also known as asparaginase-associated pancreatitis) as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase, and (iii) a Phase 2 dose ranging pharmacodynamic study in critical COVID-19 patients. There are currently no approved therapies to treat either AP or AIPT. In previous trials for both AP and COVID-19 pneumonia, patients responded well to Auxora regardless of the severity of disease at baseline. CalciMedica is also exploring potential Auxora treatment for other acute indications including acute kidney injury and acute respiratory distress syndrome.

About CARPO
CARPO is an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish efficacy in acute pancreatitis (AP). It is expected to enroll 216 patients. AP can be a life-threatening condition where the pancreas becomes inflamed, sometimes leading to pancreatic cell death or necrosis, systemic inflammation, organ failure and death. There are an estimated 275,000 hospitalizations for AP annually in the United States, of which approximately 40% present with SIRS, which can compromise the function of other tissues or organs, especially the lungs. Organ failure is responsible for much of the mortality seen in AP. There is currently no approved therapy for AP. Details of the CARPO trial are available on clinicaltrials.gov (NCT04681066).

About CalciMedica
CalciMedica is a clinical-stage biopharmaceutical company focused on developing novel CRAC channel inhibition therapies for inflammatory and immunologic diseases. CalciMedica's proprietary technology targets the inhibition of CRAC channels designed to modulate the immune response and protect against tissue cell injury, with the potential to provide therapeutic benefits in life-threatening inflammatory diseases for which there are currently no approved therapies. CalciMedica's lead product candidate Auxora™, a proprietary, intravenous-formulated CRAC channel inhibitor, has demonstrated positive and consistent clinical results in four completed efficacy clinical trials. Auxora is in development for acute pancreatitis with systemic inflammatory response syndrome and asparaginase-associated pancreatitis. CalciMedica was founded by scientists from Torrey Pines Therapeutics and the Harvard CBR Institute for Biomedical Research, and is headquartered in La Jolla, CA. For more information, please visit www.calcimedica.com.

Forward-Looking Statements
This communication contains forward-looking statements which include, but are not limited to, statements regarding the potential benefits of Auxora; and timing, design and enrollment plans of CARPO. These forward-looking statements are subject to the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. CalciMedica's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the impact of fluctuations in global financial markets on CalciMedica's business and the actions it may take in response thereto; CalciMedica's ability to successfully execute its plans and strategies which include

conducting a significant portion of the CARPO trial in India; risks associated with development of novel therapeutics, including potential delays in clinical trials and enrollment; the ability to obtain and maintain regulatory approval for CalciMedica's product candidates; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from CalciMedica's product candidates; economic, business, competitive, and/or regulatory factors affecting the business of CalciMedica generally; CalciMedica's ability to protect its intellectual property position; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" in CalciMedica's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 and elsewhere in CalciMedica's subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time and available at www.sec.gov. These documents can be accessed on CalciMedica's web page at ir.calcimedica.com/financials-filings/sec-filings.

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