CalciMedica Announces Last Patient Enrolled in Phase 2b CARPO Trial of Auxora™ in Acute Pancreatitis

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Full target enrollment of 216 patients achieved

Topline data from CARPO expected in 2Q 2024

LA JOLLA, Calif., April 24, 2024 /PRNewswire/ -- 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 the last patient has been enrolled in its Phase 2b CARPO trial of Auxora™ in acute pancreatitis (AP). Auxora is a potent and selective small molecule inhibitor of Orai1-containing CRAC channels that is being developed for use in patients with acute inflammatory and immunologic illnesses.

"We are very grateful to the patients and families that have put their trust in us throughout this enrollment process," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "We are a significant step closer to delivering a potential treatment for acute pancreatitis, for which there is currently no approved therapy. We look forward to sharing the results of this clinical trial in the coming weeks once the last patient has finished treatment and the data have been analyzed."

CARPO is an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish Auxora's dose-response and efficacy in AP with accompanying systemic inflammatory response syndrome (SIRS). The trial reached its target enrollment of 216. These patients have been randomized into four groups to receive either 2.0 mg/kg, 1.0 mg/kg or 0.5 mg/kg of Auxora or a dose of placebo intravenously every 24 hours for a total of three doses. CARPO protocol requires that treatment and observation of patients continue for 30 days, and the company plans to report topline data later this quarter.

About Auxora™

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 inflammatory and immunologic illnesses. CRAC channels are found on many cell types, including immune system cells, endothelium cells and pancreatic acinar 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) a Phase 2 trial in acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF), called KOURAGE, expected to initiate in the second quarter of 2024 and (iii) an investigator-sponsored Phase 1/2 trial, called CRSPA, being conducted in pediatric patients with asparaginase-induced pancreatic toxicity (AIPT) as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase. There are currently no approved therapies to treat either AP, AKI or AIPT. In previous trials, patients responded well to Auxora regardless of severity or cause of disease. CalciMedica is also exploring the potential of Auxora treatment for other acute indications including acute respiratory distress syndrome.

About AP

AP, or inflammation of the pancreas, can be a life-threatening condition. Moderate or severe AP sometimes leads 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, a predictor of moderate and severe disease 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 to modulate the immune response and protect against tissue cell injury, with the potential to provide therapeutic benefits in life-threatening inflammatory and immunologic 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 multiple completed efficacy clinical trials. CalciMedica is currently conducting a Phase 2b trial (called CARPO – NCT04681066) for AP with SIRS, with topline data expected in the second quarter of 2024, as well as supporting the ongoing Phase 1/2 AIPT study (called CRSPA – NCT04195347), with data expected in 2025. CalciMedica plans to initiate its Phase 2 study (called KOURAGE – NCT06374797) in AKI with associated AHRF in the second quarter of 2024 with data expected in 2025. 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, CalciMedica's planned and ongoing clinical trials and the timing, design, expected patient enrollment thereof and the expected timing for the release of data from those trials, including its Phase 2b CARPO trial of Auxora for AP with accompanying SIRS, its planned Phase 2 KOURAGE trial of Auxora in AKI with associated AHRF, and its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT; the potential benefits of Auxora for the treatment of AP, AKI and AIPT; the estimated patient populations in the United States for AP; the potential of Auxora for the treatment of other acute indications including acute respiratory distress syndrome; and the potential of CalciMedica's proprietary technology to provide therapeutic benefits in life-threatening inflammatory and immunologic diseases. 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 execute its plans and strategies; the ability to obtain and maintain regulatory approval for Auxora; results from clinical trials or preclinical studies may not be indicative of results that may be observed in the future; potential safety and other complications from Auxora; the scope, progress and expansion of developing and commercializing Auxora; the size and growth of the market therefor and the rate and degree of market acceptance thereof; 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 Annual Report on Form 10-K for the year ended December 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. The forward-looking statements contained herein are made as of the date hereof, and CalciMedica undertakes no obligation to update them after this date, except as required by law.

CalciMedica Contact:
Investors and Media
Argot Partners
Sarah Sutton/Kevin Murphy
calcimedica@argotpartners.com
(212) 600-1902

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