CalciMedica to Present Late-Breaking Positive Data, Including a Win Ratio Analysis, from Phase 2b CARPO Trial of Auxora™ in Acute Pancreatitis (AP) at the American College of Gastroenterology (ACG) 2024 Annual Scientific Meeting

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Statistically significant 100% reduction (p = 0.0027) in new-onset severe respiratory failure and 64.2% reduction (p = 0.0476) in new-onset persistent respiratory failure in combined high and medium dose Auxora patients versus combined low dose Auxora and placebo patients

Statistically significant stratified win ratio of 1.640 (p = 0.0372) for high dose Auxora compared to placebo

Clinically meaningful reduction observed for high dose Auxora patients compared to placebo in additional key endpoints: new-onset necrotizing pancreatitis and time to medically indicated discharge

Conference call and webcast to review full data set from the Ph2b CARPO trial to be held at 12 p.m. ET/ 9 a.m. PT

LA JOLLA, Calif., Oct. 30, 2024 /PRNewswire/ -- CalciMedica, Inc. (CalciMedica or the Company) (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 is announcing late-breaking positive data from the Phase 2b CARPO trial of Auxora™ in acute pancreatitis (AP) with accompanying systemic inflammatory response syndrome (SIRS) at the American College of Gastroenterology (ACG) 2024 Annual Scientific Meeting in Philadelphia, PA and virtually. Prof. Robert Sutton from the University of Liverpool and Liverpool University Hospitals NHS Foundation Trust and chair of the Steering Committee for the CARPO trial will deliver a plenary presentation entitled "A Randomized, Double-Blind, Placebo Controlled Dose Ranging Study of Auxora in Patients with Acute Pancreatitis (AP) and Accompanying Systemic Inflammatory Response Syndrome (SIRS) - CARPO."

"With the data being presented here at ACG, we see that Auxora continues to deliver across key AP endpoints, showing that the drug substantially reduced respiratory failure, necrotizing pancreatitis, and long hospital stays, which may in turn minimize patient mortality and morbidity as well as the economic burden of this disease," said Prof. Robert Sutton. "The reduction of severe respiratory failure is particularly clinically meaningful as respiratory failure is the main driver of mortality in AP patients. These data demonstrate that Auxora may be an important new tool in a critical illness with no approved therapies, and we are encouraged as we look ahead to the Phase 3 trial of Auxora in AP patients with SIRS."

"CARPO has delivered results that mirror those from previous Phase 2 trials of Auxora in other acute critical diseases and represents a significant step forward for the development of CRAC channel inhibitors in these diseases," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "The CARPO results highlight Auxora's unique immunomodulatory action coupled with direct organ tissue protection, most importantly in the lung, and provide an optimistic readthrough to the acute kidney injury, or AKI, setting, where respiratory failure is also a significant cause of mortality. With these data, we are even more encouraged about KOURAGE, our Phase 2 trial in AKI patients with respiratory failure, which we expect to read out next year."

CARPO Trial Design

The Phase 2b CARPO trial was an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish Auxora's dose-response and efficacy in AP with accompanying SIRS. The trial reached its target enrollment of 216. Patients were randomized into four groups to receive either high 2.0 mg/kg dose (n=53), medium 1.0 mg/kg dose (n=56), or low 0.5 mg/kg dose (n=52) of Auxora or a matched dose of placebo (n=53) intravenously every 24 hours for a total of three doses. Treatment and observation of patients continued for 30 days. CT scans to evaluate pancreatic inflammation and necrosis were performed at study entry and at 30 days. Patients were stratified by baseline hematocrit, a biomarker for inflammation severity, and were well-matched for all baseline characteristics with the exception that the placebo group had approximately 12% lower proportion of hyper-inflamed patients than the study overall.

Efficacy & Safety Data Presented at the ACG Annual Scientific Meeting

At ACG, Prof. Sutton will be discussing CARPO endpoints previously reported in June, including median time to solid food tolerance (up to a 50 hour reduction for Auxora patients compared to placebo) and severe organ failure including both respiratory and renal failure (up to 61.7% relative risk reduction for Auxora patients compared to placebo), and presenting new data from additional endpoints. The new data includes an integration of key endpoints of the trial into a win ratio analysis, providing a comprehensive evaluation of Auxora for the treatment of AP with SIRS.

- New-onset severe respiratory failure, defined as (i) receiving invasive mechanical ventilation or (ii) use of either high-flow nasal cannula or non-invasive mechanical ventilation for 48 hours or longer, occurred in 0% of high dose patients, 0% of medium dose patients, 8.3% of low dose patients, and 8.5% of placebo patients, representing a 100% (p = 0.0027) relative risk reduction when combined high and medium dose patients were compared to combined low

dose and placebo patients.

- New-onset persistent respiratory failure, defined as (i) severe respiratory failure or (ii) not severe respiratory failure but PaO_2 /FiO_2 of 300 or lower for 48 hours or longer and use of low-flow oxygen support, occurred in 8% of high dose patients, 1.9% of medium dose patients, 10.4% of low dose patients, and 17% of placebo patients, representing a 64.2% (p = 0.0476) relative risk reduction when combined high and medium dose patients were compared to combined low dose and placebo patients.
- New-onset necrotizing pancreatitis, measured on day 30, occurred in 29.7% of high dose patients, 40.8% of medium dose patients, 38.6% of low dose patients, and 37.0% of placebo patients, representing a relative risk reduction of approximately 20% for high dose patients compared to placebo patients.
- Median time to medically indicated discharge, defined as (i) no clinical evidence of infection necessitating continued hospitalization, (ii) solid food tolerance, and (iii) abdominal pain resolved or controlled with non-opiate medications, was 89.0 hours for high dose patients, 104.5 hours for medium dose patients, 109.5 hours for low dose patients, and 104.0 hours for placebo patients, demonstrating a reduction of 15.0 hours for high dose patients when compared to placebo.
- Long hospital stays were reduced in combined high and medium dose patients compared to combined low dose and placebo patients, with 18% vs 31% of patients in the hospital longer than 7 days, 5% vs 10% longer than 14 days, and 1% vs 6% longer than 21 days, respectively. There were no high dose patients who stayed in the hospital longer than 21 days.
- When key endpoints—all-cause mortality, new-onset severe respiratory failure, new-onset necrotizing pancreatitis, and time to medically indicated discharge—were integrated into a win ratio analysis, the high dose of Auxora outperformed placebo by a similar margin across all endpoints and delivered a stratified win ratio of 1.640 (p = 0.0372).

As in prior Phase 2 trials, Auxora provided patients with clinically meaningful improvement and was well-tolerated. There was a trend of decreasing treatment emergent serious adverse event (TESAE) rates with increasing doses of drug. Additionally, there were no drug-related TESAEs or deaths in patients receiving the high dose of Auxora.

"AP is a complex inflammatory syndrome that currently has no approved therapies, leaving a significant unmet medical need for patients and hospital systems," said Rachel Leheny, Ph.D., Chief Executive Officer of CalciMedica. "With CARPO, we believe we have now identified the most effective dose of Auxora for AP patients and have clarified how best to measure the drug's benefit to these patients. Given the complexity of issues that these patients experience, we are encouraged that the 2.0 mg/kg Auxora dose delivered a statistically significant 1.640 stratified win ratio compared to placebo. We plan to meet with the FDA to discuss the design of a Phase 3 trial of Auxora in patients with AP with accompanying SIRS."

The Company will be hosting a conference call and webcast on Wednesday, October 30, 2024 at 12 p.m. ET/ 9 a.m. PT, during which Prof. Robert Sutton will deliver his plenary presentation from the ACG Annual Scientific meeting. To join, follow the instructions below.

Participant Webcast Link: https://app.webinar.net/4EanW4A2PXk

Click on the webcast link and complete the online registration form.

Upon registering, you will be connected to the online webcast.

Participant Dial-in Numbers: 1-646-357-8785 (US) and 1-800-836-8184 (international)

If prompted by the operator, ask to join the CalciMedica Phase 2b CARPO Full Data Set & Win Ratio call.

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 has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials, including a Phase 2b trial (called CARPO) in patients with AP with SIRS and a Phase 2 trial (called CARDEA) in patients with COVID pneumonia. Auxora is currently being evaluated in a Phase 2 trial in acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF), called KOURAGE, and 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 300,000 U.S. patients hospitalized for AP annually, with an estimated 100,000 with accompanying 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™ has demonstrated positive and consistent clinical results in multiple completed efficacy clinical trials. CalciMedica has announced data for a Phase 2b trial (called CARPO – NCT04681066) in patients with AP with SIRS and completed a Phase 2 trial (called CARDEA – NCT04345614) in patients with COVID pneumonia. The Company is currently conducting a Phase 2 trial (called KOURAGE – NCT06374797) in patients with AKI with associated AHRF with data expected in 2025 and continuing to support the ongoing Phase 1/2 trial (called CRSPA – NCT04195347) in patients with AIPT 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 business strategy; the potential benefits of Auxora for treatment of AP patients and the healthcare system, including its potential to address the significant disease burden of AP; the estimated patient population and demographics of patients with AP; the Company's target patient population in AP and the likely drug dose of Phase 3 trial of Auxora for the treatment of AP; 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 2 KOURAGE trial of Auxora in AKI with associated AHRF, its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT and its planned Phase 3 trial of Auxora for AP with accompanying SIRS; plans for an end of Phase 2 meeting with the FDA for CARPO; the potential benefits of Auxora for the treatment of AP, AKI and AIPT; 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; the impact of government laws and regulations; and CalciMedica's financial position and need for additional capital. 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 June 30, 2024, and elsewhere in CalciMedica's subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the Securities and Exchange Commission 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.

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