CalciMedica Announces First Patient Enrolled in Phase 2 KOURAGE Trial of Auxora™ in Severe Acute Kidney Injury (AKI)

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Development of Auxora in AKI is supported by both clinical and pre-clinical evidence

Topline data expected in 2025

LA JOLLA, Calif., July 9, 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 announced that the first patient has been dosed in KOURAGE, the Company's Phase 2 trial evaluating Auxora™ for the treatment of severe acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF).

"AKI is a serious condition, causing about 3.7 million hospitalizations annually just in the United States," said Lakhmir Chawla, M.D., Clinical Professor of Medicine at University of California San Diego, Chief Medical Officer at ExThera Medical, and Chair of the KOURAGE Steering Committee. "Disease progression for patients with AKI can occur quickly, and those who reach Stage 2 and Stage 3 AKI face significant risk of mortality and serious morbidities such as respiratory failure. The current standard of care for these patients is limited to supportive therapy. With Auxora, CalciMedica continues to lay the foundation for a potentially revolutionary treatment for an underserved and often fatal disease."

"Auxora has shown promising data in preclinical models and prior human trials which highlight its potential as a therapeutic option for AKI, where none currently exists," said Glenn Chertow, M.D., Norman S. Coplon/ Satellite Healthcare Professor of Medicine, Professor of Epidemiology and Population Health and Health Policy at Stanford Medicine, and Member of the KOURAGE Steering Committee. "In KOURAGE, Auxora will be used to treat patients with established, moderate to severe AKI, and I look forward to reviewing the data in the coming year."

KOURAGE is a randomized, double-blind, placebo-controlled study expected to enroll approximately 150 patients with Stage 2 and 3 AKI who have AHRF and will randomize patients to receive 5 daily doses of Auxora or placebo. The study will assess patients up to day 30 following the final dosing to evaluate the number of days alive without the need for a ventilator or dialysis. The study's secondary endpoints will include a composite measure of all-cause mortality, decline in estimated glomerular filtration rate (eGFR) and the occurrence of dialysis over a 90-day period, also known as MAKE-90 (Major Adverse Kidney Events at 90 days). Topline data from KOURAGE are expected in 2025.

"Our CARDEA trial revealed that treatment of severe and critical COVID-19 pneumonia patients with Auxora reduced the reported incidence of AKI and improved the survival of patients with kidney disease," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "We demonstrated the potential benefits of Auxora in an ischemia reperfusion model of AKI that showed that the therapeutic treatment of AKI with Auxora improved kidney function as measured by estimated glomerular filtration rate and enhanced survival. These results were presented at the 29th International Conference on Advances in Critical Care Nephrology that was held in March of this year. These data contribute to the growing body of evidence supporting Auxora as a potential treatment for various acute and critical illnesses."

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, 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 KOURAGE and AKI
KOURAGE is a randomized, double-blind, placebo-controlled study that will evaluate 150 patients with Stage 2 and 3 AKI who have AHRF and are receiving oxygen by non-invasive mechanical ventilation, high flow nasal cannula or intermittent mandatory ventilation (IMV). AKI denotes a sudden reduction in kidney function, the organ's ability to clean and filter the blood. AKI can result as a complication of other serious illnesses such as sepsis, respiratory infections and failure, acute pancreatitis, trauma, surgery and burns. There are approximately 3.7 million patients hospitalized with AKI in the United States each year with approximately 1.1 million advancing to Stage 2 and Stage 3 AKI, over half of whom have associated AHRF. The risk of serious morbidities and mortality is significant for advanced Stage 2 and Stage 3 AKI patients. There are currently no approved therapies for AKI.

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 topline 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 planned and ongoing clinical trials and the timing, design, expected patient enrollment 6thereof 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 Phase 2b CARPO trial of Auxora for AP with accompanying SIRS, and its ongoing Phase 1/2 CRSPA trial of Auxora in pediatric patients with AIPT; the potential benefits of Auxora for the treatment of AKI, AP, and AIPT; the estimated patient populations in the United States for AKI; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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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