CalciMedica Announces Clinical Development of Auxora May Proceed Following FDA Review of KOURAGE Trial Interim Safety Data

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FDA reviewed a protocol amendment and interim safety data from the KOURAGE trial evaluating Auxora in AKI patients

No comments or questions were received

Confirms CalciMedica's ability to continue clinical development of Auxora across indications

LA JOLLA, Calif., June 24, 2026 /PRNewswire/ -- CalciMedica, Inc. ("CalciMedica" or the "Company") (Nasdaq: CALC), a clinical-stage biopharmaceutical company developing novel calcium release-activated calcium (CRAC) channel inhibition therapies for serious inflammatory, immunologic, and cardiopulmonary diseases, today announced that the U.S. Food and Drug Administration (FDA) has reviewed a protocol amendment and interim safety data for CalciMedica's Phase 2 KOURAGE trial in patients with Stage 2 or Stage 3 acute kidney injury (AKI) with associated acute hypoxemic respiratory failure (AHRF). Following the applicable review period, the Company has received no comments from the FDA on the submission, meaning that CalciMedica may continue to dose patients with Auxora™ in the study.

In January 2026, CalciMedica announced a pause in enrollment for the Phase 2 KOURAGE trial following a recommendation from the trial's Independent Data Monitoring Committee (IDMC) regarding a safety concern relating to a mortality imbalance that warranted reevaluation of the study design. The IDMC did not identify evidence of drug-related toxicity, and the Company's comprehensive review, performed in conjunction with external experts, reached the same conclusion while identifying imbalances in patients' baseline disease severity that necessitated revisions to the protocol design.

In March 2026, CalciMedica submitted an amendment to the KOURAGE trial to address design issues, which included refinements to patient inclusion criteria and changes to stratification methodology. The submission included a comprehensive safety assessment of the 107 patients who were dosed prior to the pause in enrollment, including cause-of-death information for all deaths and an analysis of serious adverse events (SAEs). Based on the Company's review, the observed SAEs were consistent with previous clinical experience with Auxora and did not appear to be drug related. The FDA has confirmed that the Clinical Pharmacology team of the Division of Cardiology and Nephrology has no comments regarding this submission. As the KOURAGE trial was never placed on clinical hold, and the decision to pause enrollment was made solely at the discretion of the Company, the FDA is not obligated to respond to the IND amendment. Following more than 60 days of review, the information contained in the amendment has resulted in no comments or questions from the FDA and no clinical hold communication.

CalciMedica expects feedback from the FDA on the design of a potential pivotal program evaluating Auxora in acute pancreatitis in the third quarter of 2026.

About CalciMedica
CalciMedica is a clinical-stage biopharmaceutical company developing novel calcium release-activated calcium (CRAC) channel inhibition therapies for inflammatory, immunologic, and cardiopulmonary diseases. The Company's pipeline includes Auxora™ (zegocractin), its intravenous CRAC channel inhibitor, and CM5480, its proprietary, selective oral CRAC channel inhibitor candidate. Auxora has been evaluated in more than 350 patients across completed and ongoing clinical trials and is planned to be evaluated in a Phase 1b proof-of-concept study in patients with pulmonary arterial hypertension (PAH). CM5480 is being developed as a potential chronic oral therapy for chronic inflammatory diseases such as pulmonary hypertension (PH), with IND clearance expected in mid-2027. Together, the programs are intended to establish CRAC channel inhibition as a differentiated therapeutic approach targeting both pulmonary vascular remodeling and right ventricular dysfunction in PH. 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 CalciMedica's clinical development plans for Auxora™, including in acute kidney injury and acute pancreatitis; CalciMedica's ability to continue dosing patients with Auxora in the KOURAGE trial or otherwise continue clinical development of Auxora following FDA review of the KOURAGE protocol amendment and interim safety data; CalciMedica's interpretation of the FDA's lack of comments or questions regarding the submission; the potential resumption, continuation, design, conduct, timing, enrollment or completion of the KOURAGE trial or any future clinical trial evaluating Auxora in AKI; the potential safety, efficacy, clinical utility and regulatory development path for Auxora; CalciMedica's expectation to receive feedback from FDA regarding the design of a potential pivotal program evaluating Auxora in acute pancreatitis in the third quarter of 2026; CalciMedica's plans to advance CM5480 as a potential oral therapy for PH; and the potential of CalciMedica's proprietary technology to provide therapeutic benefits in inflammatory, immunologic and cardiopulmonary 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 and CM5480; 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 and CM5480; 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 March 31, 2026, filed with the SEC on May 12, 2026, 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.

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