



CalciMedica Presents Data from Preclinical Studies of Auxora in Acute Kidney Injury at the 29th International AKI & CRRT Conference

Therapeutic treatment with Auxora shown to hasten the recovery of kidney function and improve survival in a rat model of acute kidney injury (AKI)

Preclinical results are consistent with clinical observations made with Auxora, supporting the KOURAGE trial in patients with severe AKI that will start enrolling in 2Q 2024

LA JOLLA, CA, Mar. 13, 2024 – 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 diseases, last evening presented data from preclinical studies of Auxora™ in acute kidney injury (AKI) at the 29th International Acute Kidney Injury and Continuous Renal Replacement Therapy Conference (AKI & CRRT) in San Diego, CA. David Basile, Ph.D., Professor of Anatomy, Cell Biology and Physiology at Indiana University, gave an oral and poster presentation entitled “The Store-Operated Calcium Channel Inhibitor Auxora Improves Renal Function Following Ischemia-Induced Acute Kidney Injury in Rats.”

“At AKI & CRRT, Prof. Basile discussed the most recent preclinical study of Auxora in an acute kidney injury model that used a treatment regimen of three daily doses of drug started six hours after ischemic injury, which resembles the dosing in our clinical protocol. The positive results from this study build on prior preclinical data and indicate that inhibiting Orai1 activity in an AKI model improves kidney function,” said Kenneth Stauderman, Ph.D., Founder and Chief Scientific Officer of CalciMedica. “In rats with ischemic kidney injury akin to Stage 2 AKI, Auxora was shown to provide nearly complete recovery of kidney function, as evidenced by improved glomerular filtration rate (GFR) at 72 hours after injury, while placebo-treated animals showed little improvement in GFR. In rats with kidney injury akin to Stage 3 AKI, the rats treated with placebo died while those on Auxora survived and showed modest recovery of GFR. We are excited as these studies support clinical observations of Auxora that suggest the drug may be beneficial for AKI patients.”

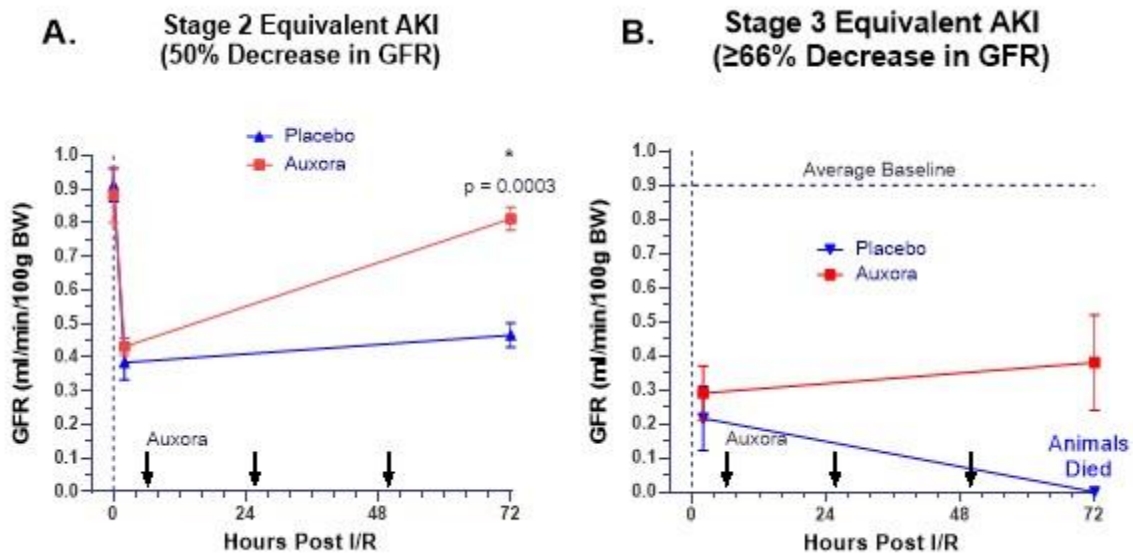
AKI is a serious acute critical illness and denotes a sudden reduction in kidney function, or the organ’s ability to clean and filter the blood, that results from a complication of critical illness. These animal model studies support observations from CalciMedica’s clinical trials, particularly CARDEA, the Company’s Phase 2 trial in patients with severe and critical COVID-19 pneumonia, where AKI was a relatively common co-morbidity or a common sequela of the disease. Compared to placebo-treated patients, Auxora-treated patients in CARDEA had lower levels of key biomarkers associated with kidney injury, lower incidence of treatment-emergent AKI and reduced mortality in those patients with decreased kidney function at the time of treatment. Additionally, previous preclinical studies conducted by CalciMedica and others suggest that Orai1 activity contributes to the activation and infiltration of pro-inflammatory Th17 cells in the kidney, which is associated with the development of AKI. CalciMedica has also shown that the active ingredient in Auxora, zegocractin, inhibits release of IL-17, which is a key pro-inflammatory cytokine from Th17 cells.

“As we initiate KOURAGE, our Phase 2 trial of Auxora in severe AKI patients with associated acute hypoxemic respiratory failure, we are encouraged to have additional supporting data showing that Auxora has beneficial activity in animal models of AKI,” said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. “Patients randomized in KOURAGE will have Stage 2 and Stage 3 AKI, so the results from Prof. Basile’s recent preclinical study, most notably the survival benefit, are particularly meaningful. Severe AKI in the presence of respiratory failure has a mortality of approximately 50% and we are heartened to see that Auxora has the potential for a positive impact on patients with this devastating disease.”

Data Presented at the AKI & CRRT Conference

The data presented at AKI & CRRT was from a series of studies referred to as Study 1 and Study 2. In Study 1, AKI was induced in a rat model through ischemia reperfusion injury (I/R), a transient ligation of the renal artery, while control animals underwent sham-surgery. Within 30 minutes of injury, the animals were treated with a single intravenous infusion of either 16 mg/kg of Auxora or placebo over a period of 4 hours. GFR, an important indicator of kidney function, was evaluated at 24 hours post-injury. Study 2 evaluated recovery of kidney function following I/R similar to Study 1 but varying in intensity to mimic different severity of disease. In Study 2, GFR was measured 2-4 hours after injury but before treatment, and treatment with 16 mg/kg of Auxora or placebo was administered at 6, 24 and 48 hours post-injury, with GFR again evaluated at 72 hours.

Results from Study 1 showed that at 24 hours post-injury, GFR was significantly higher in rats treated with Auxora 30 minutes after injury versus placebo (61%, $p < 0.05$). Additionally, animals treated with Auxora showed a reduction in Th17 cells in the kidney of approximately 50% as compared to those treated with placebo. In Study 2, in a group of animals with initial GFR reductions of approximately 50%, similar to Stage 2 AKI, GFR at 72 hours was significantly greater in Auxora-treated animals as compared to placebo-treated animals (0.81 ± 0.03 vs. 0.47 ± 0.04 ml/min/100g respectively; $p < 0.001$). In a group of animals with GFR reductions $\geq 66\%$, similar to Stage 3 AKI, placebo-treated rats experienced 100% mortality by 72 hours while Auxora-treated rats had no mortality at 72 hours and were stable, showing modest recovery of kidney function. These results indicate that Auxora has the ability to hasten the recovery of kidney function and improve survival in rat models of AKI.



Effects of Auxora on recovery of renal function after establishment of renal functional impairment. GFR is shown at 2 hours and 72 hours post I/R. Panel A: results from rats with initial loss of GFR of approximately 50% between 2-4 hr post I/R show that the recovery of GFR is greater in Auxora treated animals (n=5) compared to placebo (n=4). Panel B: results from rats with an initial loss of GFR \geq 66% show that placebo-treated rats (n=3) did not survive while Auxora-treated rats (n=2) survived. Significance by ANOVA is shown.

About AKI

Acute kidney injury (AKI) denotes a sudden reduction in kidney function, or the organ's ability to clean and filter the blood, as measured by increased serum creatinine (a cellular waste product) or decreased urine volume. AKI can result as a complication of critical illness such as sepsis, pneumonia and acute pancreatitis, and other causes such as trauma, surgery and burns. There are approximately 3.7 million patients hospitalized with AKI in the United States each year. The majority have Stage 1 AKI and recover with supportive care alone. However, approximately 1.1 million of these patients advance to Stage 2 and Stage 3 AKI, over half of whom have associated acute hypoxemic respiratory failure (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 KOURAGE

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). Patients will be stratified by classification of stage of AKI as well as the use of IMV. Patients will receive either a four-hour infusion of Auxora or placebo at 1.25 mL/kg as a first dose, after which they will receive Auxora or placebo at 1.0 mL/kg at hours 24, 48, 72 and 96. The primary endpoint of the trial will be evaluation of patients through day 30 to determine days alive, ventilator-free and dialysis-free. Secondary endpoints will include a composite

of: all-cause mortality, decrease in estimated glomerular filtration rate (eGFR), and the incidence of dialysis over a period of 90 days, also known as MAKE-90 (Major Adverse Kidney Events at 90 days).

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) 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, (iii) a Phase 2 dose-ranging pharmacodynamic study in critical COVID-19 patients and (iv) a Phase 2 trial in AKI with associated AHRF, called KOURAGE, expected to initiate in the first half of 2024. There are currently no approved therapies to treat either AP, AIPT or AKI. 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 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 for a planned 216 patients (called CARPO – NCT04681066) for AP with SIRS, with topline data expected in the first half of 2024, as well as supporting the ongoing Phase 1/2 CRSPA AIPT study (called CRSPA – NCT04195347), with additional data expected by 2H 2024. CalciMedica plans to initiate its Phase 2 KOURAGE study in AKI in 1H 2024. 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 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 planned Phase 2 KOURAGE trial of Auxora in AKI with associated AHRF, its ongoing Phase 2b trial of Auxora for AP with accompanying SIRS, its ongoing Phase 1/2 trial of Auxora in pediatric patients with AIPT, and its Phase 2 dose-ranging pharmacodynamic study in critical COVID-19 patients; the potential benefits of Auxora for the treatment of AKI, AP and AIPT; the potential of Auxora for the treatment of other acute indications including acute respiratory distress syndrome; the potential of CalciMedica's proprietary technology to provide therapeutic benefits in life-threatening inflammatory and immunologic diseases; pre-clinical and clinical studies of Auxora supporting the rationale for and design for the KOURAGE trial and the estimated patient population in the United States for AKI. 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 September 30, 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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