CalciMedica Collaborator St. Jude Children's Research Hospital Presents Data from Initial Cohort of CRSPA Study at 65th Annual ASH Meeting & Exposition

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Treatment with Auxora™ shown to potentially reduce the severity of asparaginase-associated pancreatitis, also called asparaginase-induced pancreatic toxicity, in pediatric patients with acute lymphoblastic leukemia

Auxora eliminated the need for total parenteral nutrition and resulted in a 53% reduction in days in hospital and a 40% reduction in intensive care unit days as compared to historical matched control group

None of the Auxora-treated patients had significant necrosis compared to 27% of historical control patients at 30 days

LA JOLLA, Calif., Dec. 11, 2023 /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 diseases, today announced that its collaborator, St. Jude Children's Research Hospital (SJCRH), presented data from the initial cohort of the Phase 1/2 CRSPA study of Auxora™ (zegocractin injectable emulsion) in asparaginase-induced pancreatic toxicity (AIPT) at the 65th Annual American Society of Hematology (ASH) Meeting & Exposition on Sunday, December 10, 2023, in San Diego, CA.

"It is extremely encouraging to see the results of our CRSPA study in this first cohort of patients as we continue to enroll new patients and expand to additional sites," said Sudarshan Hebbar, M.D., Chief Medical Officer of CalciMedica. "Notably, treatment with Auxora delivered positive results across multiple clinical endpoints. The elimination of the need for total parenteral nutrition, or TPN, for CRSPA patients who were able to eat on their own is particularly encouraging given that over half of the patients in the historical control group required TPN for several weeks on average. The ability to tolerate solid food correlates with pancreatic health and recovery from pancreatitis. Importantly, we saw an improvement in solid food tolerance in our Phase 2a acute pancreatitis trial, and time to solid food tolerance is the primary endpoint of our CARPO trial in adult patients with acute pancreatitis, which we expect to read out in the first half of 2024. With no approved therapies for asparaginase-induced pancreatic toxicity or acute pancreatitis on the market, we are excited about the potential benefits that Auxora could provide patients."

Investigators at SJCRH presented results from the first cohort of the CRSPA study, consisting of nine children (average age 8.2 years) with acute lymphoblastic leukemia (ALL) experiencing asparaginase-associated pancreatitis, also known as AIPT and referred to as AAP in the abstract. AIPT is a severe complication that can arise during the treatment of ALL patients, the majority of which are children, characterized by intense abdominal pain, nausea, vomiting and systemic inflammatory response syndrome (SIRS). AIPT can lead to further chronic problems such as insulin dependence, exocrine pancreatic insufficiency and chronic pain. Many of these children can no longer be treated with current asparaginase therapy (e.g., ONCASPAR™ and RYLAZE™) which can have a negative impact on their recovery from ALL. Eight of nine patients in the CRSPA study received a full regimen of 4 daily doses of Auxora at dose level 1 (30mg/m^2 on day 1 and 42mg/m^2 on days 2-4) administered as a four-hour infusion. Results from these patients were compared to a historical matched control group of 16 patients with imaging results out of a total of 51 patients who developed AIPT within 30 days of receiving asparaginase in the Total Therapy XVI study (T16).

Treatment with Auxora, as compared to the historical matched control group, was shown to have the potential to reduce the severity of AIPT in pediatric patients with ALL. Study results showed that Auxora reduced the average number of days patients spent in the hospital from 13.4 to 6.3 days. The need for intensive care unit (ICU) care was also reduced, with three control patients (18.8%) requiring ICU care compared to one treated patient (12.5%), and the average number of days in the ICU was reduced from 5 to 3 days. Additionally, no patients in the CRSPA study required TPN, compared to 68.8% in the historical matched control group, who required 27 days of nutritional support on average. Finally, blinded central reading of pancreatic imaging showed a reduction in the development of significant pancreatic necrosis (≥30%) and the severity of acute pancreatitis by CT severity index (CTSI) scoring in patients treated with Auxora compared to the historical matched cohort. Based on these results, investigators have established dose level 1 as the recommended Phase 2 dose (RP2D) of Auxora for children with ALL experiencing AIPT.

	Total 16 (T16): All AIPT	**Matched T16 AIPT cohort**	**CRSPA evaluable for efficacy**
Patients with AIPT	51	16	8
Age: mean (range)	10.3 (2.2-19.4)	9 (2.2-18.4)	8.2 (3.1-17.6)
Female (%)	17 (33.3 %)	5 (31.3 %)	3 (37.5 %)
Low-risk therapy (%)	9 (17.6 %)	1 (6.3 %)	2 (25 %)
Hospital days (range)	12.1 (2-70)	13.4 (2-27)	6.3 (5-8)
ICU needed (%)	11 (21.6 %)	3 (18.8 %)	1 (12.5 %)

ICU days mean (range)	5.1 (1-9)	5 (3-7)	3
TPN needed (%)	27 (52.9 %)	11 (68.8 %)	0
TPN days mean (range)	37.7 (3-153)	27.2 (4-63)	NA
≥30% pancreatic necrosis (%)	NA	4 (26.7%) *	0
CTSI mean (range)	NA	5.4 (0-10) *	2.4 (0-4)
CTSI ≥ 7 (%)	NA	4 (26.7%) *	0

*One patient in matched T16 cohort was unable to be evaluated for pancreatic necrosis or a CTSI score

CTSI score definitions:
0-3 mild acute pancreatitis
4-6 moderately severe acute pancreatitis
≥7 severe acute pancreatitis

About AIPT and CRSPA
AIPT is an ultra-orphan indication affecting 300-400 pediatric patients in the US each year. Asparaginase (e.g. ONCASPAR™ and RYLAYZE™), an enzyme that degrades the amino acid asparagine, which is essential for the leukemic cells to survive, is one of the mainstays of therapy in pediatric ALL patients. However, the administration of asparaginase triggers the development of AAP or AIPT in 7-10% of patients, including the over 4,000 pediatric ALL patients treated per year in the United States, with similar numbers in Europe. The first cohort in the dose-finding part of the CRSPA study consisting of 9 patients has been completed at SJCRH and investigators believe that an optimal pediatric dose for Auxora™ in this setting has been defined. The study has continued to enroll patients beyond the initial 9 patient cohort and is being expanded to additional sites. The full study plans for 24 patients at the optimal dose. Details of the CRSPA study are available on clinicaltrials.gov (NCT04195347).

About CARPO
CARPO is an international, randomized, double-blind, placebo-controlled, dose-ranging trial intended to establish efficacy in AP with accompanying SIRS. It is expected to enroll 216 patients. AP can be a life-threatening condition where the pancreas becomes inflamed, sometimes leading 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, 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 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 continuing the Phase 1/2 CRSPA AIPT study, with additional data expected by the second half of 2024. A Phase 2 study in acute kidney injury (AKI) is planned for early 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 preliminary analysis, assessment and conclusions of the results of the first cohort of the Phase 1/2 CRSPA study; the design and potential benefits of Auxora, including its potential to reduce the severity of AIPT in pediatric patients with ALL; CalciMedica's plans and expected timing for developing its product candidates and potential benefits of its product candidates; CalciMedica's ongoing and planned clinical trials; the timing of the planned initiation of a Phase 2 study in AKI; the development and outcomes of CARPO and CRSPA trial programs, including the milestones, data announcements, expected enrollment, site expansion, potential benefits of and any other potential results related thereto; and the belief that an optimal pediatric dose for Auxora for children with ALL experiencing AIPT has been defined. 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 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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