Stockholm, Sweden **July 13, 2023**

Calliditas announces supportive interim data from Phase 2 head and neck cancer trial with lead NOX inhibitor candidate, setanaxib

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced interim data from the proof-of-concept Phase 2 trial in patients with squamous cell carcinoma of the head and neck (SCCHN) with its lead NOX 1 and 4 inhibitor product candidate, setanaxib. The analysis reflects encouraging early clinical progression-free survival (PFS) results and is supportive of the presumed anti fibrotic mode of action of setanaxib.

The basis for the analysis consisted of a data set of 20 patients with recurrent or metastatic SCCHN, out of which 16 patients had evaluable tumor size and PFS related results. Twelve (12) patients had tumor biopsies before and after treatment that were evaluable for the biomarker analysis, which included transcriptomic analysis and also evaluated pathology markers such as SMA, Foxp3 regulatory T cells and PDL-1 CPS. Due to the small sample size and heterogeneity of the patient population, any inferences from the interim analysis should be treated with caution.

The transcriptomic analysis showed that the two top pathways impacted by the treatment were fibrosis-related signaling pathways (the Idiopathic Pulmonary Fibrosis Signaling Pathway and Hepatic Fibrosis/Hepatic Stellate Cell Activation Pathway), providing support for the presumed mode of action relating to modulation of activated (myofibroblastic) fibroblasts, as well as the ongoing clinical programs.

Pathology analysis showed preliminary evidence of an increase in immunological activity within tumors of patients treated with setanaxib, with favorable changes in Foxp3and PDL-1 CPS. As SMA levels at baseline were not balanced between the groups, and tumor biopsy samples were generally small, it was not possible to draw any conclusions regarding setanaxib's impact on SMA reduction.

In terms of PFS, 7 out of the 16 evaluable patients were progression-free with either stable disease or partial response, out of which 6 were in the setanaxib arm and 1 was in the placebo arm. 6 of the 7 patients were still on the study drug at the time of the data read out with the longest period on drug being reported as 21 weeks, related to a patient in the setanaxib arm.

"Based on the encouraging clinical and transcriptomic results, data clearly support the continuation of the trial, which will read out on tumor size and progression free survival in the full trial population next year. Also, it is interesting that the transcriptomic results clearly pointed to beneficial impact on 2 fibrosis-related signaling pathways, supporting the presumed mode of action as well as our pipeline programs. We are excited about the potential of setanaxib in disease areas where today treatment options are limited" said CEO Renée Aguiar-Lucander.

"We are pleased with these encouraging interim data in a patient population where additional effective treatments are needed, and look forward to completing the study in collaboration with our excellent sites and investigators" said CMO Richard Philipson.

The trial is a randomized, placebo-controlled, double-blind, proof-of-concept Phase 2 study investigating the effect of setanaxib 800 mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks (an accepted standard treatment regimen for SCCHN), in at least 50 patients with moderate or high CAF-density tumors. A tumor biopsy is taken prior to randomization and then again after at least 9 weeks of

treatment. Treatment will continue until unacceptable toxicity or tumor progression, as is typical for oncology trials. The study is expected to read out final data in 2024.

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About Calliditas
Calliditas Therapeutics is a commercial stage biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT).

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts and focus, and the prospects for setanaxib as a treatment for SCCHN. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, continued and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.