Stockholm, Sweden **July 26, 2024**

Calliditas announces positive TRANSFORM Phase 2b topline data in primary biliary cholangitis

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the Phase 2b TRANSFORM trial met its primary endpoint, showing statistically significant improvement in ALP (Alkaline Phosphatase) for both doses tested versus placebo. The trial evaluated setanaxib, a NOX enzyme inhibitor, in patients with primary biliary cholangitis (PBC) and elevated liver stiffness.

The TRANSFORM trial is a double-blind, randomized, placebo-controlled Phase 2b study investigating the effect of setanaxib 800 mg AM + 400 mg PM, ("1200 mg arm") and 800 mg BID ("1600 mg arm") over 24 weeks of treatment. The basis for the analysis consisted of a dataset of 76 patients with primary biliary cholangitis (PBC) and elevated liver stiffness.

The treatment groups were relatively well-balanced with no clinically relevant differences between the groups observed at baseline. The result is particularly encouraging as over 40% of the trial population was on dual therapy, ie was receiving UDCA (ursodeoxycholic acid) and either Ocaliva (obeticholic acid) or Bezafibrate (PPAR agonist) as base therapy and 13% were receiving all three therapies during the study, reflecting setanaxib having clinically relevant incremental benefit beyond existing standard of care. Patients treated with setanaxib showed statistically significant improvements in the primary endpoint of ALP of 19% in the 1600mg arm and 14% in the 1200mg arm and showed positive trends on liver stiffness assessed by FibroScan® at 24 weeks. Setanaxib treatment was generally well tolerated with overall number of TEAEs (treatment emergent adverse events), as well as serious TEAEs, being similar between active treatment and placebo. The frequency of TEAEs leading to study discontinuation was higher in patients receiving active treatment compared to placebo.

"It is very encouraging to see a statistically significant treatment effect in this hard-to-treat population which is already on multiple medications in this relatively small study," said Professor Dave Jones OBE; Director, NHIP Academy; Director, Newcastle Centre for Rare Disease; Professor of Liver Immunology, Newcastle University; and Honorary Consultant Hepatologist, Newcastle upon Tyne Hospitals.

"These positive data provide further clinical evidence of the potential of setanaxib in multiple rare diseases, and we are very pleased that we now have additional positive clinical evidence in support of our unique, first in class NOX platform. We also look forward to the read out of the investigator led study in IPF as well as the ongoing study in Alport syndrome in due course." said CEO Renée Aguiar-Lucander.

"I am delighted that we have seen statistically significant and clinically meaningful improvements in ALP with encouraging trends in other outcomes in this population of patients with PBC. I'd like to extend my thanks to investigators, clinical trial site staff, and most importantly patients, who have all contributed to this important study." said CMO Richard Philipson.

The company is conducting additional clinical trials with setanaxib and is expecting the investigator led Phase 2 trial in IPF (idiopathic pulmonary fibrosis) to provide top line data in Q4 2024 / Q1, 2025. There is also an ongoing Phase 2 proof of concept trial in Alport syndrome, which is expected to deliver top line data in 2025.

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The information was sent for publication, through the agency of the contact persons set out above, on July 26, 2024 at 08:00 a.m. CET.

About Primary biliary cholangitis (PBC)
PBC is a progressive and chronic autoimmune disease of the liver that causes immune injury to biliary epithelial cells, resulting in cholestasis and fibrosis. It is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the United States, where the annual incidence ranges from 0.3 to 5.8 cases per 100,000.

About Calliditas
Calliditas Therapeutics is a biopharma company headquartered in Stockholm, Sweden, focused on identifying, developing, and commercializing novel treatments in orphan indications with significant unmet medical needs. 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). Visit Calliditas.com for further information.

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. 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 and operations, the presumed mechanism of action of setanaxib, the safety and efficacy of setanaxib in PBC or other potential indications, anticipated timelines and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. The results of early clinical trials may not predict those of future, later-stage clinical trials. The clinical data presented herein involves a limited number of patients, and these results may not be replicated in larger clinical trials. 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.