Stockholm, Sweden **February 15, 2022**

First patient randomized in pivotal TRANSFORM study with setanaxib

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the first patient has been randomized in the company's pivotal phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC).

The TRANSFORM trial is a 52-week, randomized, placebo-controlled, double-blind, adaptive Phase 2b/3 trial. It will initially investigate the effect of setanaxib 1200 mg/day and 1600 mg/day versus placebo on alkaline phosphatase (ALP) reduction in patients with PBC and with elevated liver stiffness and intolerance or inadequate response to ursodeoxycholic acid (UDCA). Key secondary endpoints include change from baseline in liver stiffness, assessed by transient elastography (FibroScan®), and change from baseline in fatigue.

An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected H1 2023. The interim analysis outcome will determine which of the two doses will be selected for the Phase 3 portion of the trial.

"We are very excited to be able to launch our next pivotal trial in an orphan indication, following the recent success of our NefIgArd trial. We are committed to providing innovative solutions to address the unmet medical needs of patients with rare diseases", said CEO Renée Aguiar-Lucander.

This global study will randomize a total of ~318 patients at up to 150 investigational centres, and expects to read out top line data in H2 2024/H1 2025. As previously reported in August 2021, Calliditas received FDA Fast Track Designation for setanaxib in PBC. Further details of the TRANSFORM study can be found at www.clinicaltrials.gov, with the reference NCT05014672.

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The information was sent for publication, through the agency of the contact persons set out above, on February 15, 2022 at 10:30 a.m. CET.

About Calliditas
Calliditas Therapeutics is a 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, TARPEYO, has been approved by the FDA as the first and only treatment of IgA nephropathy, indicated for reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR of ≥1.5g/gram. Calliditas has also filed a marketing authorization application (MAA) with the European Medicines Agency (EMA) for this drug product. Additionally, Calliditas plans to initiate clinical trials with NOX inhibitor product candidates in primary biliary cholangitis and head and neck cancer. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT).

About setanaxib
Setanaxib (GKT831), a NOX1 and NOX4 inhibitor, has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, an orphan liver disease). Based on its Phase II results, Calliditas is conducting a phase 2/3 trial with setanaxib in PBC. In addition, a proof-of-concept study in head and neck cancer is planned to start in Q1 2022. Setanaxib is also being evaluated in two investigator-led clinical trials, a Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD) and a Phase II clinical trial in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs.

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 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, operations, , clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, 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.