Stockholm, Sweden **May 17, 2022**

First patient randomized in Phase 2 trial in head and neck cancer

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the first patient has been randomized in the company's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor, setanaxib.

The trial is a randomized, placebo-controlled, double-blind, proof-of-concept Phase 2 study. It will investigate the effect of setanaxib 800 mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks (the standard treatment regimen for this immunotherapy), in approximately 50 patients with moderate or high CAF-density tumours. A tumour biopsy will be taken prior to randomization and then again after at least 9 weeks of treatment. Treatment will continue until unacceptable toxicity or progression, as is typical for oncology trials.

"Today marks an important milestone for Calliditas, with the enrolment of the first patient into our proof-of-concept study in SCCHN. We believe that a successful translation into the clinic of the promising pre-clinical observations of co-administration of setanaxib and check point inhibitors, could result in important new treatment approaches for patients with CAF rich solid tumors, and we look forward to working with our clinical trial sites, investigators and site staff to successfully execute the study," said CMO Richard Philipson.

Interim biomarker analysis is targeted for Q4 2022, and the study is expected to read out final data (including impact on tumour size) in 2023. Further details of this study can be found at www.clinicaltrials.gov, with the reference NCT05323656.

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The information was sent for publication, through the agency of the contact persons set out above, on May 17, 2022, at 11:00 a.m. CET.

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, TARPEYO™ (budesonide) delayed release capsules, has been approved by the FDA and is the subject of a marketing authorization application (MAA) with the European Medicines Agency (EMA). Additionally, Calliditas is conducting a pivotal clinical trial with its NOX inhibitor product candidate setanaxib in primary biliary cholangitis and is initiating a head and neck cancer Phase 2 trial with 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).

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 and a proof-of-concept study in head and neck cancer. 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, continued FDA approval for TARPEYO, market acceptance of TARPEYO, 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.