Stockholm, Sweden **August 9, 2021**

Calliditas Receives FDA Fast Track Designation for setanaxib in PBC

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) for its lead NOX inhibitor candidate setanaxib for the treatment of patients with the chronic orphan liver disease primary biliary cholangitis (PBC). Setanaxib has previously been granted orphan drug designation for PBC in the US and Europe.

The FDA Fast Track program facilitates the expedited development and review of new drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need. The FDA created this process to expedite the delivery of important new drugs to patients, and programs with FTD can potentially take advantage of early and frequent communication with the FDA, as well as rolling submission of the marketing application.

"We are delighted to receive Fast Track designation and look forward to working closely with the FDA towards our aim of establishing setanaxib as the potential first NOX inhibitor for PBC patients," said CEO Renée Aguiar-Lucander.

In a Phase 2 clinical trial, setanaxib demonstrated evidence of anti-fibrotic activity as measured by Fibroscan, combined with a favorable tolerability profile, as well as a statistically significant impact on fatigue. Following positive results from a Phase 1 study conducted in 2020 which evaluated higher doses of setanaxib in healthy volunteers, Calliditas is planning to initiate a pivotal Phase 2/3 study in PBC, starting in 2H 2021.

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The information was sent for publication, through the agency of the contact persons set out above, on August 9, 2021, at 8:00 a.m. CET.

About Calliditas
Calliditas Therapeutics is a specialty pharmaceutical 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 candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. Calliditas read out top line data from its ongoing global Phase 3 study within IgAN and has filed for accelerated and conditional approval. If approved, Calliditas aims to commercialize Nefecon itself in the United States. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

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, a phase 2/3 trial with setanaxib in PBC is being planned. In addition, a proof-of-concept study in head and neck cancer is planned to start in the 2nd half of 2021. Setanaxib is also being evaluated in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD) as well as being studied in an investigator led 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, business plans, regulatory submissions 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, the potential for FDA acceptance for and the success and timeline of the development of setanaxib, 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.