Stockholm **September 14, 2021**

PDUFA goal date extension for Nefecon NDA in the U.S.

Calliditas Therapeutics AB (publ) (”Calliditas” or the ”Company”) (Nasdaq Stockholm – CALTX; Nasdaq – CALT), a biopharma company focused on identifying, developing and commercializing novel treatments in orphan indications, today announced that the U.S. Food and Drug Administration (FDA) has extended the PDUFA goal date for its New Drug Application (NDA) seeking accelerated approval for Nefecon to December 15, 2021.

In March 2021 Calliditas filed for FDA approval using the Accelerated Approval Program, based on the proteinuria endpoint as previously discussed with the Agency, reflecting data from the 200 patients in Part A of the NeflgArd trial.

In its review of the NDA, the FDA has requested further analyses of the NeflgArd trial data which the company has provided to the FDA. The Agency has classified these analyses as a major amendment to the NDA. The amendment mainly provides additional eGFR and other related analyses as further support of the proteinuria data provided in the NDA submission. The FDA has therefore extended the PDUFA goal date to December 15, 2021.

"Our NDA for Nefecon is the first time that the FDA is considering an approval on the basis of proteinuria as a surrogate endpoint for accelerated approval in IgA nephropathy, requiring an in-depth review process. We will continue to cooperate closely with the FDA as they complete the review of our NDA," said Renée Aguiar-Lucander, CEO at Calliditas.

For further information, please contact:
Renée Aguiar-Lucander, CEO at Calliditas
E-mail: renee.lucander@calliditas.com

Marie Galay, Corporate Communications and IR
Tel.: +44 7955 129 845, e-mail: marie.galay@calliditas.com

The information in the press release is inside information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons above, on September 14, 2021 at 3:10 pm ET.

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 candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas read out topline data from Part A of its global Phase 3 study in IgAN in November 2020 and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors 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).

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 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 and timing of FDA approval of its regulatory marketing application for Nefecon, the potential for FDA's review extension on the NDA for Nefecon to lead to marketing approval, 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.