Stockholm, Sweden **July 15, 2022**

European Commission approves Kinpeygo® for adults with primary IgA nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the European Commission (EC) has granted conditional marketing authorization for Kinpeygo® for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram. Kinpeygo is an orphan medicinal product and the first and only approved treatment for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need, with more than 50% of patients potentially progressing to end-stage renal disease (ESRD). Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA Arzneimittel AG.

The conditional marketing authorization applies in all 27 European Union Member States as well as Iceland, Norway and Liechtenstein. Calliditas will transfer the Marketing Authorization for Kinpeygo® to its commercial partner STADA, who plans to launch Kinpeygo in the EEA in the second half of 2022.

"We are excited to receive the formal approval of Kinpeygo in the EEA as the first and only EMA approved medication for this disease. We look forward to continuing to work with our European partner, Stada, as they prepare for commercialization." said CEO Renée Aguiar-Lucander.

The Kinpeygo approval is based on the efficacy and safety data of Part A of the NeflgArd pivotal Phase 3 study, an ongoing, randomized, double-blind, placebo-controlled, multicentre study conducted to evaluate Kinpeygo 16 mg once daily oral dose vs placebo in adult patients with primary IgAN. The effect of Kinpeygo, which was developed under the name Nefecon, was assessed in patients with biopsy-proven IgAN, eGFR ≥35 mL/min/1.73 m^2, and proteinuria (defined as ≥1 g/day) who were on a stable dose of recommended or maximum tolerated RAS blockade. Patients taking 16mg of Kinpeygo once daily showed a statistically significant 31% reduction in proteinuria from baseline vs 5% in the placebo arm after 9 months of treatment. After 9 months of treatment, Kinpeygo 16 mg once daily provided a statistically significant and clinically relevant 7% treatment benefit on eGFR compared to placebo (p=0.0014). This 3.87 mL/min/1.73 m2 treatment benefit at 9 months corresponded to a slight reduction from baseline of 0.17 mL/min/1.73 m2 in patients who received Kinpeygo 16 mg once daily and a deterioration from baseline of 4.04 mL/min/1.73 m2 in patients who received placebo.

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The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the contact persons set out above, on July 15, 2022 at 5.00 p.m. CEST.

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, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO™ and conditional marketing authorization by the European Commission under the trade name KINPEYGO®. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, 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).

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 EC approval for Kinpeygo, market acceptance of Kinpeygo, 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.