Stockholm, Sweden **May 19, 2022**

Calliditas receives positive CHMP opinion in IgA nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the granting of a conditional marketing authorisation 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. If confirmed by the European Commission (EC), Kinpeygo will be 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). Upon approval Kinpeygo, which was developed under the name Nefecon, will be marketed exclusively by STADA Arzneimittel AG.

The CHMP's positive opinion will now be forwarded to the EC, which has the authority to grant a marketing authorisation for Kinpeygo in the European Union (EU) member states, and which will be adopted by Iceland, Norway and Liechtenstein. A final decision by the EC on granting a marketing authorisation is anticipated in Q3 2022. Kinpeygo is already marketed under an accelerated approval in the United States under the brand name TARPEYO™.

"This is a great outcome, which reflects the strong clinical results from our Phase 3 trial. We are delighted that patients suffering from IgAN in Europe will hopefully soon be able to access a drug developed specifically to target this disease." said CEO Renée Aguiar-Lucander.

In May 2021, Calliditas announced that it had submitted a Marketing Authorisation Application (MAA) to the EMA, which had previously granted Orphan Drug Designation to this drug candidate in the treatment of IgAN. In July 2021, Calliditas and STADA announced that the two companies had entered into a license agreement to register and commercialize Kinpeygo in the European Economic Area (EEA) member states, Switzerland and the UK.

If confirmed by the European Commission (EC), Kinpeygo will be granted a conditional marketing authorisation that is based on achievement of the primary endpoint of reduction of proteinuria in Part A of the NeflgArd pivotal Phase 3 study. 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.

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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 May 19, 2022 at 2:30 p.m. CET.

About Primary Immunoglobulin A Nephropathy
Primary immunoglobulin A nephropathy (IgA nephropathy or IgAN or Berger's Disease) is a rare, progressive, chronic autoimmune disease that attacks the kidneys and occurs when galactose-deficient IgA1 are recognized by autoantibodies, creating IgA1 immune complexes that become deposited in the glomerular mesangium of the kidney. This deposition in the kidney can lead to progressive kidney damage and potentially a clinical course resulting in end-stage renal disease. IgAN most often develops between late teens and late 30s.

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. This drug product is awaiting European Commission (EC) approval following a positive CHMP opinion. Additionally, Calliditas is conducting a pivotal clinical trial with its NOX inhibitor product candidate setanaxib in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer. 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, EC authorization for KINPEYGO, commercialization plans for and 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.