

Calliditas Receives Notice of Allowance for United States Patent Application Covering TARPEYO®

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application no. 18/100,396 entitled “New Pharmaceutical Compositions.” This Notice of Allowance is expected to result in the issuance of a U.S. patent once administrative processes are completed.

The allowed claims cover a method of treating IgA nephropathy with a composition that encompasses TARPEYO® (budesonide) delayed release capsules, developed under the name “NEFECON®”. Calliditas expects the resulting patent will be Orange Book-listable, with an anticipated expiration date in 2043. The patent, when issued, will be Calliditas’ second patent for TARPEYO in the United States.

Calliditas intends to file corresponding patent applications in additional territories around the world, including Europe and China.

“When issued, our new patent will significantly strengthen TARPEYO’s intellectual property protection, further improving its unique value proposition, and providing a basis for an active program of extending patent protection of the NEFECON® franchise globally,” said CEO Renée Aguiar-Lucander.

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas
Tel.: +46 76 403 35 43, Email: asa.hillsten@calliditas.com

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 December 11, 2023 at 15:15 p.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, developed under the name NEFECON®, has been granted accelerated approval by the US FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas’ partner, STADA Arzneimittel AG. NEFECON has also been approved by China’s National Medical Products Administration and is being commercialized in China and other Asian countries by Everest Medicines (HKEX: 1952.HK).

Additionally, Calliditas is conducting a Phase 2b 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, the scope and strength of the company’s intellectual property estate, the issuance of new patents and anticipated expiration

date thereof, the listing of additional patents in the Orange Book, 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, intellectual property of the NEFECON franchise globally, continued regulatory approvals for TARPEYO, competition from other companies, revenue and product sales projections or forecasts, 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.