

European Medicines Agency Committee for Orphan Medicinal Products provides positive opinion on Calliditas' application for setanaxib in Alport syndrome

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion on the company's application for orphan drug designation in the European Union (EU) for setanaxib in Alport syndrome. The COMP opinion will now go to the European Commission, which is responsible for adopting the decision in relation to the application for orphan designation and adding it to the Community register of orphan medicinal products for human use.

The European Medicines Agency defines orphan drugs as medicinal products for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs. Companies that obtain orphan designation benefit from protocol assistance and market exclusivity once marketing authorization has been granted by the European Commission.

"We are pleased that the COMP has issued a positive opinion for orphan drug designation for setanaxib and are excited to start another clinical program in the renal space targeting an orphan indication where today there are no approved products," said CEO Renée Aguiar-Lucander.

Based on significant pre-clinical work, Calliditas targets initiation of a randomized, placebo-controlled Phase 2 clinical study evaluating setanaxib in Alport syndrome with around 20 patients in Q4 of 2023.

Alport syndrome is a genetic disorder arising from the mutations in the genes that code for type 4 collagen. The type 4 collagen alpha chains are primarily located in the kidneys, eyes, and cochlea. The condition is, thus, characterized by kidney disease, loss of hearing, and eye abnormalities. Eventually, patients present with proteinuria, hypertension, progressive loss of kidney function (gradual decline in GFR), and end-stage renal disease (ESRD).

Calliditas is currently investigating setanaxib in a Phase 2 proof-of-concept study in squamous cell carcinoma of the head and neck (SCCHN), as well as in a Phase 2b study in primary biliary cholangitis (PBC). Setanaxib is also being evaluated in an investigator-led study in idiopathic pulmonary fibrosis (IPF).

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The information was sent for publication, through the agency of the contact persons set out above, on October 5, 2023 at 10:30 a.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. 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, clinical development plans, business plans, and regulatory submissions. 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, clinical trials (including as to the timing of the Company's planned clinical trial of setanaxib in Alport syndrome), strategy, goals and anticipated timelines, competition from other biopharmaceutical 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.