

Calliditas initiates clinical study to evaluate setanaxib in Alport Syndrome

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced the initiation of a Phase 2 clinical study to evaluate setanaxib in Alport syndrome.

Calliditas is a company focused on developing and commercializing novel treatments in rare diseases with significant unmet medical needs.

This randomized, double-blind, placebo-controlled study will evaluate setanaxib in approximately 20 patients with a genetic diagnosis of Alport syndrome and significant proteinuria despite treatment with a renin-angiotensin system (RAS) blocker. The duration of treatment is 24 weeks. The objective is to evaluate the safety and tolerability of setanaxib in patients with Alport syndrome, as well as the effect of setanaxib on UPCR and eGFR compared to placebo.

"There is an urgent clinical need in Alport syndrome for treatments that delay the progression to kidney failure," said Dr Rachel Lennon, Professor of Nephrology and Honorary Consultant Pediatric Nephrologist, University of Manchester (UK), and Coordinating Investigator for the study. "Alport syndrome can occur as early as the teenage years, when it causes major disruption to learning and education. Clinical trials allow new treatments such as setanaxib to be evaluated for safety and effectiveness in Alport syndrome."

Setanaxib is also being evaluated in Phase 2 studies in squamous cell carcinoma of the head and neck, primary biliary cholangitis, and idiopathic pulmonary fibrosis.

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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, a Phase 2 proof-of-concept trial in head and neck cancer, and a Phase 2a trial in Alport syndrome 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 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.