

Calliditas announces clinical development plan for setanaxib and comments on data from Part A of NeflgArd study at today's R&D Day

Calliditas Therapeutics AB (publ) ("Calliditas") (Nasdaq OMX – CALTX; NASDAQ – CALT) today announced it will provide information on the near-term clinical development plans for setanaxib in primary biliary cholangitis (PBC) and oncology. It will also present additional data from the Part A of the NeflgArd Phase 3 study, which recently reported positive data.

In Q4 of 2020 Calliditas acquired a controlling stake in Genkyotex, which has been developing a first in class platform for NOX inhibition and where the lead compound, setanaxib has been tested in various fibrosis related indications. Following the positive results from the Phase 1 study in January of 2021, which evaluated higher doses of setanaxib in healthy volunteers, Calliditas is planning to initiate a pivotal Phase 2/3 study in PBC, starting in 2H 2021, with final design and protocol details subject to feedback from the US Food and Drug Administration (FDA). In addition, Calliditas plans to initiate a Phase 2 proof-of-concept study in head and neck cancer this year which will study administration of setanaxib in conjunction with immunotherapy targeting CAFs (cancer associated fibroblasts).

Calliditas will also provide select data from the recently concluded Part A of the Phase 3 study NeflgArd with the lead candidate drug Nefecon, for the treatment of IgA Nephropathy. The data to be presented include overall baseline characteristics, rate of discontinuation of study treatment (9.5%) and rate of discontinuation from the study (3.5%). It is also confirmed that no adverse clinical effects were seen with regards to weight gain, blood pressure or HbA1c, reflecting a safety profile in keeping with the Phase 2b trial.

In addition, presentations on the regulatory submission process, market access and commercial preparations in the US will be included.

The R&D Day will take place between 1pm and 5pm CET today and will be webcast live and accessible at: <https://tv.streamfabriken.com/calliditas-therapeutics-cmd-january-2021>.

For further information, please contact:

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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 January 20, 2021 at 08:00 a.m. CET.

About Calliditas

Calliditas Therapeutics is a specialty pharmaceutical 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 candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. Calliditas is running a global Phase 3 study within IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

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 the regulatory pathway for setanaxib, development plans for setanaxib, plans for the conduct of and likelihood of success of clinical trials of setanaxib, the regulatory pathway for Nefecon, the conduct of and likelihood of success of ongoing clinical trials of Nefecon, plans for submissions for marketing approvals, plans and strategies for commercialization of Nefecon, if approved, Calliditas' strategy, business 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 regulatory submissions for Nefecon, the continuation of Part B of the NeflgArd study, the initiation, timing for completion, and results of any clinical trials with setanaxib, Calliditas' business, operations, 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 and other filings 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.