

Stockholm, Sweden October 7, 2021

## Calliditas announces acquisition of remaining Genkyotex minority shares

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the company now controls 100% of the share capital of Genkyotex SA ("Genkyotex"), after the completion of a centralized squeeze out offer to all minority shareholders.

Genkyotex's lead product candidate, setanaxib, is a first-in-class NOX inhibitor that targets NOX 1 and NOX 4, which are major drivers of fibrogenesis in multiple organs. In Q4 2021, Calliditas plans to initiate a 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive phase 2b/3 design with setanaxib in 318 patients with primary biliary cholangitis (PBC). As previously announced in August 2021, Calliditas received FDA fast track designation for setanaxib in PBC. Calliditas will also initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021, which will investigate the administration of setanaxib in conjunction with immunotherapy targeting cancer associated fibroblasts (CAFs).

"We are delighted to have completed our acquisition of Genkyotex, which means that we now can fully integrate the business and thereby leverage the platform optimally", said CEO Renée Aguiar-Lucander.

Subsequent to the squeeze-out, Genkyotex has become a wholly owned subsidiary of Calliditas and have been delisted from the Euronext stock exchanges.

## For further information, please contact:

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The information was sent for publication, through the agency of the contact persons set out above, on October 7, 2021 at 8:00 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 also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer. 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 Calliditas' strategy, 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, the potential for FDA acceptance for and the success and timeline of the development of setanaxib, 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.