

## Positive Phase 1 results in high-dose setanaxib trial

**Genkyotex SA, a subsidiary of Calliditas Therapeutics AB (publ) (“Calliditas”) (Nasdaq OMX – CALTX; NASDAQ – CALT), today announced positive Phase 1 data demonstrating a favorable safety and pharmacokinetic profile of high-dose setanaxib, Genkyotex’s lead asset.**

The Phase 1 study demonstrated that setanaxib is well tolerated at the doses tested, with no safety signal or dose-limiting toxicity being identified. The results provide an opportunity for the company to pursue a pivotal Phase 2/3 clinical trial in patients with primary biliary cholangitis (PBC), based on interactions with the FDA. The study assessed the safety and pharmacokinetics of oral setanaxib at selected doses in 46 healthy adult male and female subjects. The trial consisted of a single ascending dose (SAD) part and a multiple ascending dose (MAD) part with dosing up to 1600mg/day.

Previously, doses of up to 800 mg/day were evaluated in a 24-week Phase 2 trial in PBC patients. In that trial, setanaxib dosed at 800 mg/day achieved reductions in markers of cholestasis, including alkaline phosphatase, and in multiple non-invasive markers of liver fibrogenesis, including liver stiffness and PRO-C3 and C3M. Significant improvement in fatigue was also achieved. All doses tested in that trial were well-tolerated, with no safety signal compared to placebo.

“This result provides a foundation for a clinical development program using higher doses of setanaxib across a variety of orphan indications. This includes the potential to launch a pivotal phase 2/3 trial with a clearly differentiated drug candidate in PBC but will also allow us to further explore a select number of kidney related orphan diseases in which inflammation and fibrosis play a part.”, said CEO Renée Aguiar-Lucander.

Calliditas acquired 62.7% of the share capital and voting rights of Genkyotex, in November 2020, before submitting a simplified public mandatory offer to the shareholders of Genkyotex on 26 November 2020. Calliditas controls 86.2% of the share capital and total number of votes of Genkyotex.

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### **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](http://www.calliditas.com) for further information.

### **About Genkyotex**

Genkyotex (Euronext Paris and Brussels: GKTX) is a leader in NOX therapies. Its unique therapeutic approach is based on a selective inhibition of NOX enzymes, which amplify disease processes such as fibrosis, inflammation,

pain processing, cancer development, and neurodegeneration. Genkyotex's discovery platform enables the identification of orally available small-molecules that selectively inhibit specific NOX enzymes. From this, Genkyotex has developed a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate setanaxib, a NOX1 and NOX4 inhibitor, demonstrated clinical evidence of anti-fibrotic activity in liver fibrosis and improvement of fatigue in patients in a Phase II trial in primary biliary cholangitis (PBC, a fibrotic orphan disease). Setanaxib is also being evaluated in investigator-initiated Phase II clinical trials in Type 1 Diabetes and in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs.

### **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 planned and ongoing clinical trials of setanaxib, 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 filings submissions for setanaxib, the ongoing and planned clinical trials of 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.