

## **Calliditas Announces Agreement to Acquire Controlling Interest in Genkyotex SA**

**Transaction adds late-stage orphan pipeline asset and platform in inflammation and fibrosis. Calliditas to acquire 62.7% of Genkyotex for €20.3M in cash at €2.80 per share in an off-market transaction. Following the closing of the control transaction a mandatory simplified cash tender offer on the same terms for the remaining outstanding shares would be launched. Total consideration for 100% of Genkyotex would amount to ~€32M, not including milestones of up to €55M payable upon regulatory approvals of setanaxib.**

Calliditas Therapeutics AB (publ) (“Calliditas” or the Company) (Nasdaq OMX – CALTX; NASDAQ - CALT) announced today that the Company has reached an agreement to acquire a controlling interest in Genkyotex SA (“Genkyotex”) (Euronext Paris & Brussels: FR0013399474 – GKT), a leader in NOX inhibition therapies.

Genkyotex’s lead clinical candidate, setanaxib (GKT831), is in development for Primary Biliary Cholangitis (PBC), a chronic orphan liver disease resulting from progressive destruction of the bile ducts in the liver. In a Phase 2 clinical trial, setanaxib demonstrated evidence of anti-fibrotic activity combined with a favorable tolerability profile, as well as a statistically significant impact on fatigue. In April 2020, Genkyotex completed an End of Phase 2 meeting with the US Food and Drug Administration (FDA) and in June 2020 obtained scientific advice from the European Medicine Agency’s (EMA) Scientific Advice Working Party (SAWP) that provide a path forward for the late stage development and potential registration of setanaxib in PBC.

“We believe this transaction represents an exciting expansion of our pipeline in orphan diseases related to inflammation and fibrosis”, says Calliditas’ CEO Renée Aguiar-Lucander. “We believe Genkyotex’s novel NOX inhibition technology may have broad clinical utility not just in PBC, but as a platform therapy with the potential to target other fibrotic indications, including Primary Sclerosing Cholangitis (PSC), selected kidney diseases and Idiopathic Pulmonary Fibrosis (IPF), in which an investigator led Phase 2 trial is expected to start recruitment later this year.”

“We look forward to leveraging our strong late stage clinical team, CMC and regulatory expertise as well as our learnings from our Phase 3 Nefecon program to navigate and execute an efficient path forward for setanaxib. We continue to deliver on our strategy focusing on adding late stage assets with an orphan focus and encouraging data in patients to build a company focused on delivering solution for patients with diseases with high unmet needs”, Ms. Aguiar-Lucander concludes.

Calliditas has agreed to acquire through an off-market block trade 7,236,515 ordinary shares of Genkyotex representing 62.7% of the share capital and voting rights of Genkyotex<sup>1</sup> from Genkyotex's largest shareholders and management team (the “Block Sellers”)<sup>2</sup> for a total consideration of €20.3M payable in cash at closing (€2.80 per ordinary share) representing a 25% premium over Genkyotex’s volume weighted average price (VWAP) over the preceding month immediately prior to this announcement and non-transferable contingent rights to receive additional cash payments on confirmation of regulatory approvals or marketing authorizations of setanaxib, as described below. The off-market block trade is expected to close in early October 2020 and remains subject to customary conditions precedent, including the clearance from the French Minister of Economy and Finance regarding foreign investments into France. Calliditas will finance the block trade from its cash reserves.

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<sup>1</sup> Based on the total number of issued shares and voting rights of Genkyotex on the date of this press release (11,548,562)

<sup>2</sup> The Block Sellers are Andera Partners (25,3%), Eclosion 2 (12,1%), Vesalius Biocapital (9,4%), Neomed Inovation (8,1%), N5 Investments (0,6%), Wellington Partners (4,2%), Elias Papatheodorou (1,3%), Philippe Wiesel (1%) and Alexandre Grassin (0,6%).

Calliditas is seeking to acquire all outstanding Genkyotex shares and, as soon as reasonably practicable after and subject to completion of the off-market block trade, in compliance with French and Belgian securities law, Calliditas will file with the French Financial Market Authority (*Autorité des Marchés Financiers* – the “AMF”) a mandatory simplified cash tender offer for the remaining Genkyotex shares on the same terms as the block trade, €2.80 per share in cash and non-transferable contingent rights as further described below. The tender offer will be followed by a squeeze-out of the non-tendered shares under the same terms (including the contingent rights) if the legal requirements are met. Total acquisition cost would in such case amount to approximately €32.3M with total contingent rights amounting to a maximum of €55M, subject to future regulatory approvals of setanaxib.

The Block Sellers and the Genkyotex shareholders who tender their shares in the centralized tender offer will be eligible to the following additional cash payments (expressed in relation to 100% of the Genkyotex shares on a fully diluted basis) on confirmation of regulatory approvals or marketing authorizations of setanaxib no later than within ten years of the closing of the tender offer:

- €30M on approval of setanaxib for a first indication by the FDA;
- €15M on approval of setanaxib for a first indication by the European Commission (EC); and
- €10M on approval of setanaxib by the FDA or the EC for either IPF or type 1 diabetes (unless such milestone already has been paid out for such indication by the FDA or the EC as per above).

Bryan Garnier & Co acted as financial advisor to Calliditas in this transaction. Latham & Watkins LLP and Vinge acted as legal advisers to Calliditas.

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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 August 13, 2020 at 07:00 a.m. CET.*

*This press release does not constitute an offer to purchase, or a solicitation of an offer to sell, any securities of Genkyotex. The documentation relating to the tender offer which, if filed, will state the terms and conditions of the tender offer, will be submitted to the review of the AMF. Investors and shareholders are strongly advised to read the documentation relating to the tender offer when it becomes available, if the offer is filed, as well as any amendments and supplements to those documents as they will contain important information about Calliditas, Genkyotex and the proposed transaction.*

*The transaction is notably subject to the obtaining of required regulatory authorizations and other customary conditions. The tender offer would only be filed with the AMF after such conditions have been fulfilled and the off-market block trade has been closed.*

*This press release must not be published, broadcast or distributed, directly or indirectly, in any country in which the distribution of this information is subject to legal restrictions. The tender offer will not be open to the public in jurisdictions in which its launch is subject to legal restrictions. The publication, broadcasting or distribution of this press release in certain countries may be subject to legal or regulatory restrictions. Therefore, persons located in countries where this press release is published, broadcasted or distributed must inform themselves about and comply with such restrictions. Calliditas disclaims any responsibility for any violation of such restrictions.*

### **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 is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. Its unique platform enables the identification of orally available small-molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, setanaxib (GKT831), a NOX1 and NOX4 inhibitor has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease). Based on its positive Phase II results, a phase 3 trial with setanaxib in PBC is being planned. Setanaxib is also being evaluated in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD). A grant from the United States National Institutes of Health (NIH) of \$8.9 million was awarded to Professor Victor Thannickal at the University of Alabama at Birmingham (UAB) to fund a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs. The core component of this program is a Phase 2 trial with setanaxib in patients with IPF scheduled to recruit patients in the course of 2020. This product candidate may also be active in other fibrotic indications.

### **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 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, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" 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.