

Updated regulatory plans for NEFECON in China

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that partner Everest Medicines (HKEX 1952.HK) plans to submit an NDA for NEFECON in China in the second half of 2022.

Everest received Breakthrough Therapy Designation (BTD) from the China Center for Drug Evaluation, National Medical Products Administration (CDE,NMPA) in December, 2020 and have completed enrollment of the 60 Chinese patients required to complement the submission of the global data set from the NeflgArd trial. Everest plans to conduct an interim analysis of the Chinese patients and this is expected to lead to a regulatory submission in China in 2H of 2022.

“We are excited about the possibility of a significantly earlier potential approval in China, and are happy to support our partner Everest in their endeavors to bring the first approved medicine for IgA nephropathy to Chinese patients,” said CEO Renée Aguiar-Lucander.

As previously reported, in 2019 Calliditas entered into a license agreement to develop and commercialize NEFECON in Greater China and Singapore for the chronic autoimmune kidney disease IgA Nephropathy (IgAN). In March 2022, Calliditas expanded this partnership to include South Korea.

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The information was sent for publication, through the agency of the contact persons set out above, on March 18, 2022 at 8:00 a.m. CET.

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, TARPEYO™ (budesonide) delayed release capsules has been approved by the FDA and is the subject of a marketing authorization application (MAA) with the European Medicines Agency (EMA). Additionally, Calliditas is conducting a pivotal clinical trial with its NOX inhibitor product candidate setanaxib in primary biliary cholangitis and is initiating a head and neck cancer Phase 2 trial with 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, commercialization efforts, business plans, regulatory submissions, clinical development 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, continued FDA approval for TARPEYO, market acceptance of TARPEYO, 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



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