

Stockholm, Sweden

November 15, 2022

## **Calliditas' partner Everest Medicine's New Drug Application for Nefecon is accepted by the China NMPA**

**Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the Chinese regulatory authority National Medical Products Administration ("NMPA") has accepted Everest Medicines' (HKEX 1952.HK, "Everest") New Drug Application ("NDA") for Nefecon. The acceptance brings Nefecon, approved and marketed in the U.S. under the name TARPEYO® and in the E.U. as Kinpeygo®, an important step closer to potentially becoming the first-ever approved therapeutic option indicated for primary IgAN treatment in China.**

In December 2020, the NMPA recommended Breakthrough Therapy Designation ("BTD") for Nefecon for the treatment of IgAN. Chronic kidney disease is one of the most serious public health problems in China, where IgAN is estimated by Everest to affect around five million people.

"It is exciting that Everest's NDA has been accepted by the NMPA, providing a path forward to address the very significant patient population suffering from IgAN in China. We look forward to continuing our collaboration as we focus on bringing novel solutions to patients" said CEO Renée Aguiar-Lucander.

In June 2019, Calliditas entered into a license agreement with Everest to develop and commercialize Nefecon in Greater China and Singapore in IgAN. This agreement was extended to include South Korea in March 2022.

### **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 November 15, 2022 at 08:00 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, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, 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 prospective regulatory approval and marketing of Nefecon in China, 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 regulatory approvals for TARPEYO and Kinpeygo and additional regulatory approvals for Nefecon, including in China, market acceptance thereof, 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.