

China CDE/NMPA Recommends Priority Review for Nefecon for the Treatment of Primary IgA Nephropathy

Calliditas Therapeutics AB (publ) (“Calliditas”) partner Everest Medicines (HKEX 1952.HK) today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has recommended Priority Review for the New Drug Application (NDA) of Nefecon for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of rapid disease progression.

In November 2022 the NMPA accepted Everest’s NDA for Nefecon, leading to an expected regulatory decision in 2H 2023. Priority review has the potential to accelerate the regulatory review, as per Mr Rogers Luo, CEO of Everest.

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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

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