

## Calliditas provides a regulatory update on EMA process for Nefecon

**Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) can be expected in Q2, 2022.**

In its review of the marketing authorisation application (MAA) for NEFECON, the CHMP has informed us that they will issue an additional list of questions related to manufacturing related information which will result in the opinion from EMA slipping into the second quarter. The continued review does not relate to the safety or efficacy of NEFECON, and there are no plans for an oral explanation.

“Targeting an opinion in Q1 was ambitious in light of the fact that this is the first time the EMA has reviewed a drug for this indication,” said CEO Renée Aguiar-Lucander. “We are confident that we will be able to address the few remaining questions in a timely manner and we have been highly encouraged by our interactions to date with EMA, and look forward to continuing to work with them towards an approval.”

Calliditas submitted an MAA for NEFECON in May 2021. NEFECON was granted accelerated approval by the FDA in December of 2021 under the brand name TARPEYO™. For indication details please visit <https://www.tarpeyo.com/>.

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*The information was sent for publication, through the agency of the contact persons set out above, on March 22, 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 EMA review and approval for NEFECON, market acceptance of NEFECON/TARPEYO, safety or efficacy of NEFECON/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 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.