

## **EMA Grants Accelerated Assessment Procedure for Nefecon for the Treatment of IgA Nephropathy**

**Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that its lead product candidate Nefecon, a novel oral formulation targeting down regulation of IgA1 for the treatment of primary IgA Nephropathy (IgAN), has been granted accelerated assessment procedure by the European Medicine Agency’s (EMA) Committee for Human Medicinal Products (CHMP).**

Accelerated assessment, which may be granted when the CHMP concludes that the product is of major public health interest and major therapeutic innovation pursuant to Article 14 (9) of Regulation (EC) No 726/2004, reduces the timeframe for the EMA to review a marketing authorization application (MAA.) Typically, evaluating an MAA can take up to 210 procedure days, but accelerated assessment reduces the maximum timeframe for review of the application for marketing authorization to 150 days (excluding clock-stops). Calliditas expects to submit an MAA to the EMA in Q2 2021.

“We are very excited that CHMP has decided to grant us accelerated assessment, which supports the significant unmet medical need in IgAN. We look forward to engaging with EMA over the coming months with the goal to be able to bring the first approved product to patients with IgAN as soon as possible,” said CEO Renée Aguiar-Lucander.

If approved, Nefecon could be available to patients in Europe in H1 2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease modifying.

### **For further information, please contact:**

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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 April 23, 2021 at 8:30 a.m. CET.*

### **About Calliditas**

Calliditas Therapeutics is a 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 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 Nefecon**

Nefecon is a patented oral formulation of a potent and well-known active substance – budesonide – for targeted release. The formulation is designed to deliver the drug to the Peyer’s patch region of the lower small intestine, where the disease originates, as per the predominant pathogenesis models. Nefecon is derived from the TARGIT technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse like fashion only when it reaches the lower small intestine. The combination of dose and optimized release profile is required to be effective in patients with IgAN, as shown in a large Phase 2b trial, completed by Calliditas. In addition to its potent local effect, another advantage

of using this active substance is that it has very low bioavailability, i.e. around 90% of it is inactivated in the liver before it reaches the systemic circulation. This means that a high concentration can be applied locally where needed but with only very limited systemic exposure and side effects.

#### **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, including the therapeutic potential of Nefecon, our plans for regulatory submissions in Europe, the intended benefits of the EMA's accelerated assessment procedure and the availability of Nefecon to patients in Europe, if approved. 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, our planned applications to seek marketing approvals from regulatory agencies in the U.S. and Europe, acceptance by regulatory agencies with respect to the filing and approval of our regulatory marketing applications for Nefecon, our additional planned studies of Nefecon due to our intended use of the accelerated approval pathway with the FDA and the conditional approval pathway with the EMA, the potential launch and commercialization of Nefecon, if approved, 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.