

## Calliditas Announces Full Enrollment of the Phase 3 NeflgArd Trial

**Calliditas Therapeutics AB (publ) (“Calliditas”) (Nasdaq OMX – CALTX; NASDAQ – CALT) today announced that all 360 patients have been enrolled for the global Phase 3 clinical trial NeflgArd, which investigates the effect of Nefecon® versus placebo in patients with primary IgA nephropathy (IgAN).**

The NeflgArd trial consists of two parts: Part A and Part B. Part A, which forms the basis for potential regulatory submissions and approvals, provided data on the efficacy and safety of Nefecon. Calliditas read out positive topline data from Part A of the trial on 8 November 2020, announcing that the study met its primary endpoint, reduction in proteinuria, and key secondary endpoint stabilization of eGFR. It also showed that Nefecon was generally well-tolerated.

Part B is designed to be a confirmatory post-market approval observational trial to confirm long-term renal protection and assess the difference in kidney function between treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. The 360-patient population of the Phase 3 trial includes the further 160 patients enrolled in addition to the 200 patients from Part A.

“To have fully enrolled our Phase 3 pivotal trial is a great milestone, even more so as we achieved this during the pandemic, which reflects the commitment of investigators and patients, as well as that of our experienced clinical team.” said Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

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### **About Calliditas**

Calliditas Therapeutics is a specialty pharmaceutical 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 IgA nephropathy, as shown in a large Phase 2b trial, completed by the company. 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 the regulatory pathway for Nefecon, plans for submissions for marketing approvals, plans and strategies for commercialization of Nefecon, if approved, the conduct of Part B of the NeflgArd clinical trial, Calliditas' strategy, business 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 regulatory filings and submissions for Nefecon, the continuation and prospects for the success of Part B of the NeflgArd study, Calliditas' business, operations, 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 and other filings 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.