

## First Patient Dosed in NeflgArd Open Label Extension Study

**Calliditas Therapeutics AB (publ) ("Calliditas") today announced that the first patient has been dosed in the global open-label extension (OLE) of the Phase 3 NeflgArd study. OLE offers a 9-month treatment with Nefecon to all qualifying patients who have completed the NeflgArd study and will evaluate the efficacy and safety of Nefecon treatment in patients with IgA Nephropathy (IgAN).**

This study will evaluate patients who have completed the Phase 3 study NeflgArd, which achieved both its primary and key secondary endpoints in the Part A topline data read out on November 8, 2020. All patients will continue on RAS inhibitor therapy (ACEs and/or ARBs) and be treated for 9 months with Nefecon in the OLE study.

At the end of the treatment period, change in urine protein to creatinine ratio (UPCR) and change in estimated glomerular filtration rate (eGFR) will be evaluated. Further, a comparison between treatment naïve and those patients who received Nefecon in the Phase 3 NeflgArd study will be made. Three months after completion of treatment, all patients have a scheduled follow up visit.

"This trial will provide us with information regarding retreatment and will add to the sizeable data set of patients which have already completed efficacy and safety related trials with Nefecon. We are also glad to be able to provide the active drug to all patients having completed the NeflgArd trial, irrespective of treatment arm, following the positive topline data readout in Part A of the NeflgArd study showing stabilization of eGFR in the treatment arm at 36 weeks", said CEO Renée Aguiar-Lucander.

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*The information was sent for publication, through the agency of the contact persons set out above, on February 4, 2021 at 8:30 a.m. CET.*

### **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 also planning to conduct clinical trials with NOX inhibitors in PBC and oncology. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and The Nasdaq Global Select Market (ticker: CALT).

### **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 and the OLE 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 submissions for Nefecon, the continuation of Part B of the NeflgArd study and the OLE 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.