

## **The 200<sup>th</sup> patient's last visit completed in Part A of NeflgArd supporting topline readout in pivotal Phase 3 trial in Q4, 2020**

**Calliditas Therapeutics AB (publ) ("Calliditas") today announced that the last visit of the 200<sup>th</sup> patient has taken place in Part A of the pivotal NeflgArd Phase 3 study.**

The NeflgArd trial is studying the effect of Nefecon versus placebo in patients with IgA nephropathy (IgAN) at approximately 150 sites in 19 countries. It has a substantially similar design to the successful Phase 2b NEFIGAN trial, the results of which were published in the Lancet in 2017. The first patient in NeflgArd was randomized in November 2018, and in December 2019 Calliditas announced the full recruitment of Part A, encompassing 200 patients required to support a regulatory submission for potential market approval in the US and Europe (Part A). Topline data for the subjects included in Part A will read out in Q4 of 2020, and subject to positive data Calliditas plans to submit applications for market approval with regulatory agencies in the United States and the European Union in the first half of 2021.

"This is consistent with our communication that our Phase 3 trial remains on track to read out in Q4 of this year. We will now focus on ensuring a timely database lock in order to enable us to present top line data in this quarter. We are very excited to have reached this important milestone and look forward to sharing the trial results as they become available." 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.

### **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. 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, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" 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



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