Stockholm, Sweden **December 19, 2019**

Completion of recruitment of Part A of the NefIgArd pivotal Phase 3 clinical trial by year end

Calliditas Therapeutics AB (publ) ("Calliditas") today announced that 198 out of a total of 200 patients required for Part A of the Company's pivotal Phase 3 study NefIgArd, have been randomized. Top line readout of Part A of the study can thus be expected in Q4 2020.

The remaining 2 patients are expected to be randomized before the end of the year based on the large number of patients in screening. The study will continue to recruit an additional 160 patients during 2020 for Part B of the trial. With the recent approval by Chinese regulators of Everest Medicine's IND (Investigational New Drug Application), the recruitment of patients during 2020 is expected to include Chinese sites, which will enhance the recruitment rate and ensure completion of the trial on a timely basis.

The NefIgArd trial is studying the effect of Nefecon versus placebo on proteinuria in patients with IgAN at approximately 140 sites in 19 countries. The first patient was randomized in November 2018.

On the basis of positive results from Part A, Calliditas plans thereafter to file for market approval with regulatory agencies in the United States and the European Union. NefIgArd has a substantially similar design to the successful Phase 2b NEFIGAN trial of 150 patients, the results of which were published in the Lancet in 2017.

In September 2019, Calliditas obtained written feedback from the US Food and Drug Administration (FDA) indicating agreement to modify the design of Part B, which is a post-approval confirmatory part of the trial, focused on validating proteinuria as a surrogate marker. This modification significantly reduces the number of patients required in Part B and shortens the duration of the overall trial. In October 2019, the Company also received positive advice from the European Medicines Agency (EMA) related to the revised confirmatory Part B design, as well as alignment on the path forward towards conditional approval in the European Union.

"We are extremely pleased to announce that we have achieved the rare milestone of completing recruitment for this critical part of our orphan study on budget and on time. I am grateful to all the investigators, clinicians and personnel involved at the sites all over the world, as well as the Calliditas team which has put in an enormous amount of hard work and dedication to make this possible. It reflects our commitment to the patient community to continue to work relentlessly to bring appropriate and approved medications to market as soon as possible," said Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

"We are excited about the positive outcome of our interactions with the regulatory authorities this year, and we have worked intensively with distinguished KOLs and expert statisticians in order to achieve this result, which truly reflect what collaboration, focus, effort and ingenuity from a dedicated team can accomplish. We are very proud of our collective accomplishments and our continued focus on bringing Nefecon to patients with this disease."

The information in the press release is such that Calliditas Therapeutics AB (publ) is required to disclose pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, at 08:00 CET on December 19, 2019.

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About Calliditas
Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden. It is focused on developing high quality pharmaceutical products for patients with a significant unmet medical need in niche indications, in which the Company can partially or completely participate in the commercialization efforts. The Company is focused on the development and commercialization of the product candidate Nefecon, a unique formulation optimized to combine a time lag effect with a concentrated release of the active substance budesonide, within a designated target area. This patented, locally acting formulation is intended for treatment of patients with the inflammatory renal disease IgA nephropathy (IgAN). Calliditas Therapeutics is running a global Phase 3 study within IgAN and aims to commercialize Nefecon in the US. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit www.calliditas.com for further information.