Stockholm, Sweden **September 3, 2019**

Positive feedback from FDA significantly benefits ongoing NefIgArd pivotal Phase 3 study

Calliditas Therapeutics AB (publ) ("Calliditas") today announced that it has obtained written feedback from the US Food and Drug Administration (FDA) that will have a significant impact on the ongoing pivotal Phase 3 study, NefIgArd, with Calliditas' leading drug candidate Nefecon for the chronic autoimmune kidney disease IgA Nephropathy (IgAN).

Calliditas has had an active dialogue with the FDA around the NefIgArd study during the year and has received acceptance of a design change of the Part B of the NefIgArd study, which significantly simplifies and enhances the design of the confirmatory part of the study.

The main implications of updated FDA advice

- Acceptance of a two-year eGFR based end point for the Part B of the study, resulting in a considerably shorter study, reducing the overall time from six to around three and a half years.
- Read out for full approval two years after last patient is randomized.
- Study size reduced from 450 to 360 patients for Parts A and B in total, with significant positive impact on overall costs and recruitment time.
- Option to initiate a roll over for NefIgArd patients into a repeat-dosing study subsequent to them completing the two-year pivotal study. This would allow for placebo patients to cross over, and for additional data to be generated related to disease modifying effect.

"We are extremely pleased with the outcome of our interactions with the FDA, which will have a very positive impact on the conduct of our pivotal study," said Renée Aguiar-Lucander, CEO of Calliditas. "This is great news for patients as well, as it will enable us to complete the confirmatory part of the trial in a timely manner without potential impact on patient access to the marketed drug. It also has significant benefit with regards to the overall cost and timelines of the program."

The NefIgArd trial is studying the effect of Nefecon versus placebo on proteinuria in patients with IgAN at approximately 140 sites in 19 countries. First patient dosed was in November of 2018, and results from the top line readout of 200 dosed patients are expected in the second half of 2020. On the basis of positive results, Calliditas plans thereafter to file for market approval with regulatory agencies. NefIgArd follows the successful Phase 2b NEFIGAN trial of 150 patients, the results of which were published in the Lancet in 2017 and which had a substantially similar design to the Phase 3 study now underway.

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 07:00 am CET on September 3, 2019.

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About Calliditas Therapeutics

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 two-step 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 plans to commercialize Nefecon in the US. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit www.calliditas.com for further information.