Stockholm, Sweden **October 1, 2019**

Positive interactions with EMA provide route to conditional marketing authorization of lead candidate Nefecon

Calliditas Therapeutics AB (publ) ("Calliditas") today announced that the European Medicines Agency (EMA) has provided positive guidance related to a conditional marketing authorization (CMA) of the company's lead compound Nefecon, currently in Phase 3 clinical trials in IgA nephropathy (IgAN).

In a written response received from EMA, the agency agreed that it could support CMA assessment, subject as usual to the strength of the full data set presented at the time of filing, which will also include an analysis by Calliditas related to the likelihood of achieving success in Part B of the ongoing Phase 3 study NefIgArd.

This positive outcome reflects the availability of strong Phase 2b data, a critical statistical analysis approach and a clear and compelling Phase 3 study design. The NefIgArd study was initiated in November 2018 and is currently running, with expected readout of topline data in second half of 2020.

"We are very happy to have received this guidance by EMA/CHMP, which is the result of a common journey and constructive discussions with the agency since 2017. It is exciting that we continue to see positive support for an accelerated route to market for our drug in IgAN. It also provided acceptance of the revised Part B design and hence a similar regulatory pathway in both the US and EU", said Calliditas' CEO Renée Aguiar-Lucander.

"It is exciting to be pioneering a data driven approach for accelerated/ conditional approval in this disease and combined with the late stage of our Phase 3 trial, we believe that we are in a very strong position to launch the first approved drug in this indication, which is very rewarding", she continued.

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 October 1, 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.