

The pivotal Phase 3 clinical trial NeflgArd Part A fully recruited

Calliditas Therapeutics AB (publ) (“Calliditas”) today announced the full recruitment of all 200 patients required for Part A of the company’s pivotal Phase 3 study NeflgArd. Top line readout of Part A of the study is expected in Q4 2020.

The study will continue to recruit an additional 160 patients during 2020 in order to complete Part B of the trial. The NeflgArd trial is studying the effect of Nefecon versus placebo on proteinuria in patients with IgA nephropathy (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 to file for market approval with regulatory agencies in the United States and the European Union. NeflgArd 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.

The information was submitted for publication, through the agency of the contact person set out below, at 08:00 CET on December 23, 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.