Stockholm, Sweden **November 13, 2018**

First patient enrolled in pivotal clinical phase 3 study NEFIGARD with lead candidate Nefecon

Calliditas Therapeutics AB (publ) ("Calliditas") today announced that the first patient has been enrolled in the company's pivotal clinical phase 3 study NEFIGARD in patients with IgA nephropathy (IgAN).

The NEFIGARD trial will study the effect of Nefecon versus placebo on proteinuria in patients with IgAN. Based on positive results from the first 200 dosed patients, Calliditas plans to file for market approval with regulatory agencies. Top line data is expected in H2 2020. It follows the successful Phase 2b trial of 150 patients, NEFIGAN, which results were published in the Lancet in 2017 and which had a substantially similar design to the Phase 3 study now underway.

"As outlined at our IPO, we have a clear strategy to maximize the potential of Nefecon as a disease-modifying treatment for patients suffering from this chronic autoimmune disease. I am very pleased to announce the study start, which is a critical step as we accelerate the development of Nefecon through Phase 3 clinical trials", commented Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

The study will randomize a total of 450 patients to a 9-month, once-daily, oral treatment with either Nefecon or placebo at approximately 150 clinical sites in 19 countries. Further details of the NEFIGARD study can be found at www.clinicaltrials.gov, with the reference NCT03643965.

"We are pleased to announce the randomization of the first patient in this important phase 3 study. We have previously shown good efficacy and safety of Nefecon in the comprehensive NEFIGAN study, which as of today is the only successful, placebo-controlled Phase 2b study in this indication. We expect to see a similar study result of reducing proteinuria and stabilizing the kidney function of patients coupled with the benign safety profile we have seen so far," commented Jens Kristensen, Chief Medical Officer of Calliditas Therapeutics.

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 16:20 CET on November 13, 2018.

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About Calliditas
Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden, 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. Calliditas Therapeutics aims to take Nefecon through a global Phase 3 study to commercialization. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit www.calliditas.com for further information.

About Nefecon

Nefecon is a potential treatment for patients with IgAN at risk of developing ESRD. It is a proprietary oral formulation of budesonide, designed to deliver budesonide to the ileum where the so-called Peyer's patches, which harbor the majority of B-cells producing IgA antibodies, are found. By delivering budesonide locally instead of systemically, Nefecon greatly reduces the side-effect burden observed with high dose steroid treatment while optimizing the effective dose level of the drug where it is required. Budesonide has been used to treat patients with asthma, inflammatory bowel disease and allergic rhinitis for over 35 years. It is rapidly degraded soon after entering the circulatory system, making it an ideal basis for drugs such as Nefecon because local delivery to disease tissue minimizes the systemic effects seen with other corticosteroids. Nefecon has been granted orphan drug designation for IgAN by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About IgA Nephropathy (IgAN)

IgA nephropathy (IgAN) – also known as Berger's disease – is the most common form of glomerulonephritis, a chronic inflammatory condition of the kidney, in the Western world. IgAN is a serious autoimmune, progressive disease that leads to decreasing kidney function over the course of 10 to 20 years. Up to 50 percent of patients diagnosed with IgAN will progress to end-stage renal disease (ESRD), a disease state requiring dialysis or kidney transplant for survival due to insufficient kidney function within 20 years. IgAN is an orphan disease, designated as an orphan indication in both the US and Europe. IgAN affects approximately 130,000–150,000 people in the US and about 250,000 people in Europe. Today, there are no approved treatments for IgAN. Today's standard of care treatment regimens entails primarily established, generic drugs such as blood pressure lowering agents to alleviate symptoms, complemented by off-label use of systemic corticosteroids.