Stockholm, Sweden **February 12, 2019**

Calliditas Therapeutics granted orphan drug designation by the FDA for Primary biliary cholangitis

Calliditas Therapeutics AB (publ) (”Calliditas”) today announced that the US Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to the company for the treatment of Primary biliary cholangitis (PBC). More information about the ODD has been posted on www.fda.gov.

PBC, previously known as primary biliary cirrhosis, is an autoimmune disease of the liver, where common symptoms are tiredness, itching and, in more advanced cases, jaundice. PBC is a rare disease, affecting approximately 4.3 people in 10,000 in US. It is much more common in women, with a ratio of at least 9:1 female to male.

The company plans to discuss the regulatory pathway for this indication in consultation with the FDAand investigate the most appropriate way forward for this patient population.

“We are very pleased to receive ODD in the US for the treatment of PBC. This confirms the high unmet medical need and further encourages us to continue to explore orphan indications in which we could leverage our existing expertise. This is a disease with few medical alternatives today, but with a lot of exciting research taking place”. , commented Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

Earlier in February 2019, the company was granted ODD by the FDA for AIH. The company plans to agree the regulatory pathway for this indication in consultation with the FDA later this year.

Also, the company is currently running a global, pivotal Phase 3 with study for the treatment of the rare disease IgA nephropathy (IgAN), and which has already obtained ODD by the FDA and the European Medicines Agency (EMA). Top line data for IgAN is expected in H2 2020.

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 11:15 CET on February 12, 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 (tícker: CALTX). Visit www.calliditas.com for further information.

About Primary biliary cholangitis (PBC)
PBC, previously known as primary biliary cirrhosis, is an autoimmune disease of the liver. It results from a slow, progressive destruction of the small bile ducts of the liver, causing bile and other toxins to build up in the liver, a condition called cholestasis. Further slow damage to the liver tissue can lead to scarring, fibrosis, and eventually cirrhosis.

Common symptoms are tiredness, itching and, in more advanced cases, jaundice. In early cases, there may only be changes in blood tests. PBC is a rare disease, affecting approximately 4.3 people in 10,000, in US. It is much more common in women, with a sex ratio of at least 9:1 female to male.

About Orphan Drug Designation (ODD)

The FDA Orphan Drug Act (ODA) provides for granting special status to a drug or biological product to treat a rare disease that affect fewer than 200,000 people in the US. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits, protocol assistance and up to seven years of US marketing exclusivity from time of approval of a Biologics License Application (BLA).