Stockholm, Sweden **August 12, 2019**

Strategic in-licensing related to autoimmune hepatitis in the US market

Calliditas Therapeutics AB (publ) ("Calliditas") today announced that it has exclusively in-licensed Budenofalk 3mg oral capsule for the US market from the German pharmaceutical company Dr. Falk Pharma GmbH ("Dr. Falk"). The agreement covers all indications for the US market, excluding orphan indications outside of liver targets. Initially, Calliditas will leverage Dr. Falk's clinical trial data and expertise in liver indications, such as autoimmune hepatitis (AIH) with a view to accelerate approval and market access.

The deal has an initial upfront payment of €1.5m and foresees additional regulatory related payments, subject to market approval from the US Food and Drug Administration (FDA). The total deal value amounts to €40m, including future sales milestones and comes with typical royalties.

AIH is an orphan liver disease which Calliditas estimates affects about 60 – 80,000 people in the US and for which there today is no approved treatment. Calliditas initially aims to leverage positive clinical trial data from Dr. Falk to support discussions with the FDA, focused on receiving guidance on the clinical program necessary to obtain an approval to market the product in the US.

"This is an excellent opportunity for us to accelerate our development program in AIH and hopefully reduce both cost and time to market, while forging a relationship with a pre-eminent European player in the pharmaceutical space. In addition, potentially having two separate products in our core market gives us more flexibility regarding positioning and pricing across different orphan indications," commented Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

Calliditas will now focus on preparing for a meeting with the FDA, which preliminarily is planned for Q1 of 2020. Based on positive feedback regarding the regulatory path for the product from the FDA, a late stage clinical program could then be initiated in 2020.

Dr. Roland Greinwald, Managing Director of Dr. Falk Pharma GmbH, commented: "Dr. Falk is delighted to partner with Calliditas and to support Calliditas in making Budenofalk oral capsules available as a new treatment option for AIH in the US market.".

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 14:40 CET on August 12, 2019.

For further information, please contact:
Mikael Widell, Head of Communications
Email: mikael.widell@calliditas.com
Telephone +46 703 11 99 60

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.

About Dr. Falk Pharma GmbH

Dr. Falk Pharma GmbH is one of the leading companies worldwide in gastroenterology with its products being sold in more than 60 countries. Its pharmaceuticals are used successfully to treat inflammatory bowel disease, cholestatic liver disease, irritable bowel syndrome, constipation, and for colon cleansing prior to colonoscopies. The Falk Foundation, which is associated with the company, provides medical information via international symposia, forums, postgraduate courses and literature services. Over the past 45 years the Falk Foundation has sponsored more than 200 international Falk symposia and workshops in which over 100,000 researchers and physicians from 110 countries have come together to advance knowledge in gastroenterology and hepatology.

For more information on Dr. Falk Pharma GmbH, please see https://www.drfalkpharma.de

About Autoimmune hepatitis (AIH)

Autoimmune hepatitis (AIH), formerly called lupoid hepatitis, is a chronic, autoimmune disease of the liver that occurs when the body's immune system attacks liver cells causing the liver to be inflamed. Common initial symptoms include fatigue or muscle aches or signs of acute liver inflammation including fever, jaundice, and right upper quadrant abdominal pain. The disease is detected by tests showing abnormal liver function.

Anomalous presentation of MHC class II receptors on the surface of liver cells, possibly due to genetic predisposition or acute liver infection, causes a cell-mediated immune response against the body's own liver, resulting in autoimmune hepatitis. This abnormal immune response results in inflammation of the liver, which can lead to further symptoms and complications such as fatigue and cirrhosis, and if untreated, to liver failure. The disease may occur in any ethnic group and at any age but is most often diagnosed in patients between age 40 and 50 and is more common in women.