Stockholm, Sweden **July 21, 2021**

Calliditas Therapeutics and STADA partner to register and commercialize specialty therapy for IgA Nephropathy in Europe

- **Calliditas and STADA partner to bring a specialty therapy focused on downregulating IgA1 to European patients. If approved, it would be the first-ever approved treatment in the EU for chronic autoimmune kidney disease IgA Nephropathy (IgAN)**
- **Partnership for this oral orphan-drug candidate combines Calliditas' drug-delivery expertise with STADA's pan-European marketing and sales expertise, including for specialty and nephrology medicines**
- **Deal covering European Economic Area (EEA) member states, Switzerland and the UK is valued at a total of 97.5 million EUR ($115m), plus royalties**

Stockholm, Sweden; Bad Vilbel, Germany. 21 July 2021 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") and STADA Arzneimittel AG ("STADA") announced today that they have entered into a license agreement to register and commercialize a novel specialty drug candidate for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in the European Economic Area (EEA) member states, Switzerland and the UK.

Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of 20M EUR ($24m) upon signing and up to an additional 77.5M EUR ($91m) in future payments linked to pre-defined regulatory and commercialization milestones. STADA is also obligated pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

The partnership relates to a novel oral formulation, developed under the project name 'Nefecon', of a potent and well-known active substance – budesonide – designed to target down regulation of IgA1 with a view to be disease modifying. If approved, this value-added specialty medicine, which received an EU orphan-drug designation in 2016, would be the first treatment authorized in the European Union for IgAN, a rare autoimmune disease. IgAN, also known as Berger´s disease, is a serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end stage renal disease and thus requiring dialysis or a kidney transplant. Prevalence in Europe is estimated at 4 in 10,000, translating into approximately 200,000 patients.

"We are excited to be entering into this partnership with STADA to bring this IgAN therapy to market in Europe, where there is a significant unmet medical need for this patient population. We look forward to working in close collaboration with STADA to pursue marketing authorization with the goal of bringing the first ever EU-approved medication in IgAN to patients as soon as possible, utilizing STADA's extensive marketing and sales platform throughout Europe," said Renée Aguiar-Lucander, CEO of Calliditas.

"This partnership, which leverages Calliditas' drug-delivery expertise and clinical data in this under-served patient population, further validates STADA's position as a go-to-partner for specialty pharmaceuticals, as well as for generics and consumer health products," commented STADA CEO Peter Goldschmidt. "This value-added novel formulation for a large orphan indication will complement STADA's offerings in nephrology, where we have built strong expertise over more than a decade through our epoetin zeta biosimilar and where we continue to place a clear strategic focus on seeking further opportunities to bring new options to patients."

The novel formulation is designed to deliver the drug to the Peyer's patch region of the lower small intestine, where the disease originates as per the predominant pathogenesis models. The formulation uses a unique two-step technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse like fashion only when it reaches the ileum in the lower small intestine. In addition to its potent local effect, another advantage of using this active substance is that it has very low bioavailability, with around 90% being inactivated in the liver before it reaches the systemic circulation. This means that a high concentration can be applied locally where needed, whilst limiting systemic exposure.

On May 28, 2021, Calliditas announced that the company had, under the drug-development candidate name Nefecon, submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for a novel oral formulation of budesonide targeting down regulation of IgA1 for the treatment of primary IgAN. The company also filed an application for accelerated approval in the US on March 15, 2021 and was granted priority review in April 2021. The commercial brand name for this therapy in Europe will be determined and disclosed at a later date.

Calliditas´ oral formulation has been granted Accelerated Assessment procedure by the Committee for Human Medicinal Products (CHMP) within the European Medicines Agency, which is intended to expedite access to drugs that the CHMP considers to be of major therapeutic interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Accelerated assessment reduces the maximum timeframe for review of the MAA to 150 days (excluding clock-stops).

IgAN is designated as an orphan disease in both the US and Europe. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment. Orphan incentives consist of ten years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.

If approved, the product could be available to patients in Europe in the first half of 2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease modifying.

Torreya acted as exclusive financial advisor to Calliditas on the transaction.

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The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the Calliditas contact person set out above, on July 21, 2021 at 8:45 a.m. CET.

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2020, STADA achieved group sales of EUR 3,010.3 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 713.3 million. As of December 31, 2020, STADA employed 12,301 people worldwide.

About Calliditas
Calliditas Therapeutics is a biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans, regulatory submissions and focus, as well as Calliditas's partnership with STADA, the parties' plans with respect to registration and commercialization of the specialty therapy, the terms of the collaboration and the intended benefits therefrom, the regulatory pathway and interactions for Nefecon, including timing of review and assessment of the candidate, and the intended benefits of regulatory designations such as Accelerated Assessment and orphan disease. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, the conduct of Calliditas's partnership with STADA, the potential for regulatory acceptance for and the success and timeline of its regulatory marketing application for Nefecon, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.