Press release

STADA and Calliditas announce the filing for full marketing authorization for Kinpeygo® in the EU

- Request submitted to EMA to convert conditional marketing authorization to standard marketing authorization for Kinpeygo treatment for primary IgA nephropathy
- Submission to the CHMP for full approval is based on the full two-year data set from the Phase 3 NefIgArd clinical trial, as recently published in leading medical journal *The Lancet*
- Kinpeygo is the first and only approved treatment in Europe for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need.

Bad Vilbel, Germany/Stockholm, Sweden – 28 September 2023 – Partners STADA and Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced the submission of a request to the European Medicines Agency (EMA) for the Committee for Medicinal Products for Human Use (CHMP) to convert the conditional marketing authorization for Kinpeygo®, their treatment for primary IgA nephropathy (IgAN), to a standard, or "full", marketing authorization.

Kinpeygo is currently approved under conditional approval to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram. This was granted in the interest of public health because the medicine addresses an unmet medical need, and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required.

Kinpeygo is the first and only approved treatment in Europe for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need. STADA, which holds European

commercial rights, in September 2022 already launched the IgAN medicine in Germany and is working to extend patient access to other countries.

The submission to the CHMP for full approval is based on the full two-year data set from the Phase 3 NefIgArd clinical trial, as recently published in leading medical journal *The Lancet*[1]. This randomized, double-blind, multicenter study assessed the efficacy and safety of Kinpeygo – developed under the project name Nefecon® – dosed at 16 mg once daily versus placebo on a background of optimized renin-angiotensin system inhibitor (RASi) therapy in adult patients with primary IgAN. The trial met its primary endpoint, with Kinpeygo demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in estimated glomerular filtration rate (eGFR) over the two-year period of 9 months of treatment with Kinpeygo or placebo and 15 months of follow-up off drug.

"By filing for a standard marketing authorization with the EMA, based on the full dataset published in the *Lancet* journal, STADA and Calliditas are optimistic about bringing this important Specialty therapy for unmet medical need in chronic kidney disease to more people with IgAN in Europe," commented STADA's Head of Global Specialty, Bryan Kim.

"The eGFR treatment benefit observed across the entire study population, irrespective of UPCR levels, provides further evidence that targeting IgAN at its source can offer patients a treatment that holds the promise of being disease-modifying. We are pleased to be able to provide the EMA with the full results of our Phase 3 study, and we look forward to interactions with the regulatory agency regarding full approval of Kinpeygo," stated Renée Aguiar-Lucander, Chief Executive Officer of Calliditas Therapeutics.

[1] Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NefIgArd): 2-year results from a randomised phase 3 trial - The Lancet

About Kinpeygo

Kinpeygo is an oral, modified-release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Kinpeygo is a 4 mg modified-release capsule and is enteric coated and designed to remain intact until it reaches the ileum. Each capsule contains coated beads of budesonide that target mucosal B-cells present in the ileum, including the Peyer's patches, which are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy.

About the NeflgArd Study

The global clinical trial NefIgArd is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Kinpeygo 16 mg once daily vs placebo in adult patients with primary IgAN (N=364), as an addition to optimized RAS inhibitor therapy. Part A of the study included a 9-month blinded treatment period and a 3-month follow-up period. The primary endpoint was UPCR, and eGFR was a secondary endpoint. Part B included a 12-month observational period off drug and assessed eGFR over the entire 2-year period for patients who were treated with the Kinpeygo or placebo regimen in Part A. The full NefIgArd trial met its primary endpoint. Topline data from the full NefIgArd study were reported on March 12, 2023.

About Primary Immunoglobulin A Nephropathy

Primary immunoglobulin A nephropathy (IgA nephropathy or IgAN or Berger's Disease) is a rare, progressive, chronic autoimmune disease that attacks the kidneys and occurs when galactose-deficient IgA1 is recognized by autoantibodies, creating IgA1 immune complexes that become deposited in the glomerular mesangium of the kidney. This deposition in the kidney can lead to progressive kidney damage and potentially a clinical course resulting in end- stage renal disease. IgAN most often develops between late teens and late 30s.

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2022, STADA achieved group sales of EUR 3,797.2 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 884.7 million. As of 31 December 2022, STADA employed 13,183 people worldwide.

About Calliditas

Calliditas Therapeutics is a commercial stage 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, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT).

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, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts and focus. 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, continued and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts 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.

STADA information for journalists:

STADA Arzneimittel AG - Media Relations
Stadastrasse 2-18
61118 Bad Vilbel - Germany
Phone: +49 (0) 6101 603-165
E-Mail: press@stada.de
Or visit us on the Internet at www.stada.com/press

STADA information for capital market participants:

STADA Arzneimittel AG - Investor & Creditor Relations
Stadastrasse 2-18
61118 Bad Vilbel – Germany
Phone: +49 (0) 6101 603-4689
Fax: +49 (0) 6101 603-215
E-mail: ir@stada.de
Or visit us on the Internet at www.stada.com/investor-relations

Calliditas - For further information, please contact:

Åsa Hillsten, Head of Investor Relations, Calliditas
Tel.: +46 76 403 35 43, email: asa.hillsten@calliditas.com