Stockholm, Sweden **August 15, 2023**

Calliditas Therapeutics announces full results from the NefIgArd Phase 3 trial published in The Lancet

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced publication in *The Lancet* of the full data from the Phase 3 NefIgArd Study with Nefecon® (TARPEYO® (budesonide) delayed release capsules/Kinpeygo®) in adults with Primary IgA nephropathy (IgAN). The Phase 3 trial met the primary endpoint, estimated glomerular filtration rate (eGFR), with Nefecon demonstrating significant kidney protective effect over placebo.

"IgAN is a severe debilitating disease leading to end-stage kidney disease in more than 50% of the patients. The full results from NefIgArd study demonstrate the ability of Nefecon to slow kidney function deterioration and as such to slow down the disease progression and delay the need for dialysis and kidney transplantation," said Jonathan M. Barratt, M.D., Mayer Professor of Renal Medicine. University of Leicester. "These results also support the key role of the gut immune system in the pathogenesis of IgAN and the differentiated effect of Nefecon treating the disease at its origin."

The analysis published in *The Lancet* shows that Nefecon demonstrated a highly statistically significant and clinically relevant benefit compared to placebo in eGFR over the two-year period of 9-months of treatment with Nefecon and 15-months of follow-up off drug. After the two-year period, there was a 6.11 mL/min/1.73 m^2 decline in eGFR in the Nefecon arm compared with a 12.0 mL/min/1.73 m^2 decline in the placebo arm, corresponding to a difference in two-year eGFR total slope of 2.95 mL/min/1.73m^2 per year (p<0·0001). The reduction in UPCR observed with Nefecon treatment was durable, reflecting a long-lasting treatment effect during the 15-month follow-up period off treatment. Patients treated with Nefecon maintained a greater than 30% proteinuria reduction from the end of the 9-month treatment through the entire follow-up period, with a reduction in UPCR of over 50% observed at 12 months.

Nefecon was generally well tolerated, with the majority of treatment-emergent adverse events (TEAE) being mild or moderate, and with TEAEs leading to discontinuation of study drug in <10% of patients. Objective measures of mean weight and blood pressure showed non-clinically relevant changes.

" The data demonstrated supportive 2-year total slope analyses that were not only statistically significant but also clinically meaningful, showcasing a sustained treatment benefit. The eGFR benefit was observed across the entire study population, irrespective of baseline urine protein-to-creatinine ratio (UPCR)," said Richard Lafayette, M.D., F.A.C.P., Stanford Healthcare and lead author of the publication. "The sustained reduction of proteinuria and the protective effect on kidney function support the disease-modifying effect of Nefecon. These robust results provide new hope for patients and reinforce Nefecon's potential to make a meaningful difference in the lives of those affected by this challenging disease."

"We are thrilled to see the NefIgArd Phase 3 data published in *The Lancet*, highlighting these important results for the IgAN patient community," said Renée Aguiar-Lucander, Chief Executive Officer at Calliditas. "The established long-term eGFR benefit reflects Nefecon's ability to slow kidney function decline by targeting the origin of the disease and providing a differentiated and disease-modifying treatment alternative."

Nefecon is currently approved under accelerated approval to reduce proteinuria in adults with Primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 g/g. In June 2023, Calliditas submitted a supplemental new drug application (sNDA) to the United States Federal Drug Administration (FDA) seeking full approval

based on the full NefIgArd study data. Calliditas is supporting its partner STADA Arzneimittel AG with the filing for full approval with the European Commission and the UK MHRA in 2H of 2023.

The peer-reviewed article in *The Lancet* can be viewed here.

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The information was sent for publication, through the agency of the contact persons set out above, on August 15, 2023 at 08:00 a.m. CET.

Indication

TARPEYO® (budesonide) delayed release capsules is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a confirmatory clinical trial.

Important Safety Information

Contraindications: TARPEYO is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of TARPEYO. Serious hypersensitivity reactions, including anaphylaxis, have occurred with other budesonide formulations.

Warnings and Precautions

Hypercorticism and adrenal axis suppression: When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur. Corticosteroids can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to surgery or other stress situations, supplementation with a systemic corticosteroid is recommended. When discontinuing therapy *[see Dosing and Administration]* or switching between corticosteroids, monitor for signs of adrenal axis suppression.

Patients with moderate to severe hepatic impairment (Child-Pugh Class B and C, respectively) could be at an increased risk of hypercorticism and adrenal axis suppression due to an increased systemic exposure to oral budesonide. Avoid use in patients with severe hepatic impairment (Child-Pugh Class C). Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

Risks of immunosuppression: Patients who are on drugs that suppress the immune system are more susceptible to infection than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in susceptible patients or patients on immunosuppressive doses of corticosteroids. Avoid corticosteroid therapy in patients with active or quiescent tuberculosis infection; untreated fungal, bacterial, systemic viral, or parasitic infections; or ocular herpes simplex. Avoid exposure to active, easily transmitted infections (eg., chicken pox, measles). Corticosteroid therapy may decrease the immune response to some vaccines.

Other corticosteroid effects: TARPEYO is a systemically available corticosteroid and is expected to cause related adverse reactions. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataracts, a family history of diabetes or glaucoma, or with any other condition in which corticosteroids may have unwanted effects.

Adverse reactions: In clinical studies, the most common adverse reactions with TARPEYO (occurring in ≥5% of TARPEYO patients and ≥2% higher than placebo) were hypertension (16%), peripheral edema (14%), muscle spasms (13%), acne (11%), dermatitis (7%), weight increase (7%), dyspnea (6%), face edema (6%), dyspepsia (5%), fatigue (5%), and hirsutism (5%).

Drug interactions: Budesonide is a substrate for CYP3A4. Avoid use with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine. Avoid ingestion of grapefruit juice with TARPEYO. Intake of grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide.

Use in specific populations

Pregnancy: The available data from published case series, epidemiological studies, and reviews with oral budesonide use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with IgAN. Infants exposed to in utero corticosteroids, including budesonide, are at risk for hypoadrenalism.

Please see **Full Prescribing Information**.

About TARPEYO[1]

Calliditas has introduced TARPEYO, the first FDA-approved therapy for the treatment of the autoimmune renal disease primary IgA Nephropathy, or IgAN, to reduce proteinuria in adults with primary IgAN who are at risk of rapid disease progression, generally a UPCR≥1.5g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

TARPEYO is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. TARPEYO is as a 4 mg delayed 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. It is unclear to what extent TARPEYO's efficacy is mediated via local effects in the ileum vs systemic effects.

About the NefIgArd Study

The global clinical trial NefIgArd is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of TARPEYO 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 TARPEYO 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.[2,3] 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.[3,4]

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.