Stockholm, Sweden **October 19, 2022**

Kidney International Publishes Results from NefIgArd Phase 3 Trial Evaluating TARPEYO® (budesonide) in IgA Nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced Kidney International has published the successful results from NefIgArd Part A, their pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter study.

The publication highlights the safety results and efficacy data related to both proteinuria and estimated glomerular filtration rate (eGFR) for patients treated with TARPEYO while on background of optimized and stable renin-angiotensin system inhibitor (RASi) therapy.

"The publication of data from our NefIgArd Phase 3 study will address physician requests related to more comprehensive information regarding the mode of action and efficacy of TARPEYO, the first and only FDA-approved treatment specifically designed for this disease," said Renée Aguiar-Lucander, Chief Executive Officer of Calliditas. "We are excited to share these data and see this as reinforcing evidence of the differentiation we believe that TARPEYO represents, as well as its potential to be disease modifying. "

IgAN is a chronic autoimmune disease with a significant burden of disease, with more than 50% of patients progressing to end-stage kidney disease within 20 years of initial diagnosis.[2]

The peer-reviewed article can be viewed here.

INDICATION and IMPORTANT SAFETY INFORMATION

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 benefit 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 for TARPEYO here.

About the NefIgArd Study
The global clinical trial NefIgArd is an ongoing 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=360) as an addition to optimized RASi 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 is a confirmatory validation study for full approval that will assess eGFR over 2 years for patients who were treated with the TARPEYO or placebo regimen in Part A.

The trial met its primary objective in Part A of demonstrating a statistically significant reduction in urine protein creatinine ratio, UPCR or proteinuria, after 9 months of treatment with 16 mg once daily of TARPEYO compared to placebo. Patients taking TARPEYO plus RASi (n=97) showed a statistically significant 34% reduction from baseline vs 5% with RASi alone (n=102) at 9 months, resulting in UPCR reduction of 31% (16% to 42%) p=0.0001.[3]

At 12 months, a 53% reduction in UPCR from baseline was seen in the TARPEYO plus RASi-treated group (n=97) vs 9% with RASi alone (n=102). Additional data presented prior to or beyond the primary endpoint of 9 months or from subgroup analyses should be interpreted cautiously.[3]

At 9 months, there was a 3.87 mL/min/1.73 m2 difference in eGFR absolute change with TARPEYO plus RASi vs RASi alone (-0.17 vs. -4.04).[4]

In a separate analysis at 9 months (based on the analysis of the full patient population including patients who received rescue treatment), absolute change in eGFR was -0.6 mL/min/1.73 m2 with TARPEYO plus RASi (n=97) vs -4.0 mL/min/1.73 m2 with RASi alone (n=102).[3] These interim data were not prospectively controlled for multiplicity and need cautious interpretation. The clinical significance of these results is unknown. Confirmatory clinical trial results are required to draw any conclusions. It has not been established whether TARPEYO has demonstrated a benefit in slowing kidney function decline in patients with IgAN.

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 are recognized by autoantibodies, creating IgA1 immune complexes that become deposited in the glomerular mesangium of the kidney.[5,6] 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.[6,7]

About Calliditas
Calliditas Therapeutics is a commercial stage biopharma company headquartered 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 is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT).

Visit www.calliditas.com for further information.

About TARPEYO
Calliditas has introduced TARPEYO, to reduce proteinuria in adults with primary IgAN 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.[1]

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 was designed as a 4 mg delayed release capsule and is enteric coated so that it would 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.[1]

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. 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 FDA approval for TARPEYO, market acceptance of TARPEYO and the potential impact of TARPEYO for the IgA nephropathy community, 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.

For further information, please contact:
Marie Galay, Investor Relations Manager, Calliditas
Tel: +44 79 55 12 98 45; email: marie.galay@calliditas.com

Sky Striar, Calliditas Media Contact, LifeSci Communications Tel:
+1.617.797.6672; email: sstriar@lifescicomms.com

The information was sent for publication, through the agency of the contact persons set out above, on October 19, 2022 at 3:30 p.m. CET.

References: 1. TARPEYO. Prescribing Information. Calliditas Therapeutics AB; 2021. **2.** Hastings, M. C., Bursac, Z., Julian, B. A., Villa Baca, E., Featherston, J., Woodford, S. Y., Bailey, L., & Wyatt, R. J. (2018). Life Expectancy for Patients From the Southeastern United States With IgA Nephropathy. Kidney Int Rep, 3(1), 99-104. https://doi.org/10.1016/j. ekir.2017.08.008 **3.** Data on file. Calliditas Therapeutics AB **4.** Barratt, J., Lafayette, R., Kristensen, J., et al. (2022). Results from part A of the multi-center, double-blind, randomized, placebo controlled NefIgArd trial evaluated targeted-release formulation of budesonide for the treatment of primary https://doi.org/10.1016/j.kint.2022.09.017 **5.** Barratt, J., & Feehally, J. (2005). IgA nephropathy. J Am Soc Nephrol, 16(7), 2088-2097. https://doi.org/10.1681/ASN.2005020134 **6.** Barratt, J., Rovin, B. H., Cattran, D., et al. (2020). Why Target the Gut to Treat IgA Nephropathy? Kidney Int Rep, 5(10), 1620-1624. https://doi.org/10.1016/j.ekir.2020.08.009 **7.** Jarrick, S., Lundberg, S., Welander, A., et al. (2019). Mortality in IgA Nephropathy: A Nationwide Population-Based Cohort Study. J Am Soc Nephrol, 30(5), 866-876. https://doi.org/10.1681/ASN.2018101017