Stockholm, Sweden **January 28, 2022**

Calliditas Therapeutics Announces Commercial Availability and Initial Sales of TARPEYO™

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced the commercial availability and initial sales of TARPEYO™ (budesonide), the first and only FDA approved treatment for IgA nephropathy, indicated for reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. IgAN is a rare, progressive autoimmune disease, which has a high unmet need with more than 50% of patients potentially progressing to end-stage renal disease (ESRD).[1]

"Our team has been working diligently to make TARPEYO available to patients as quickly as possible. That we have already started shipping product speaks to providers' desire for additional treatment options, underscoring the significant unmet need in this indication," said Andrew Udell, President North America. "To support this launch, we have built what we consider to be world class medical affairs, marketing, market access and sales teams capable of quickly responding to the needs of these patients. Now that our drug is commercially available, we are focused on making sure that patients who may benefit from TARPEYO can access treatment. To that end, we are proud to offer a robust patient support program that offers services and resources including financial assistance, where appropriate."

Calliditas is committed to working with payers and healthcare providers across the United States to help ensure that all patients prescribed TARPEYO have access to it. To assist patients and their healthcare providers who would prescribe TARPEYO, Calliditas has launched a comprehensive patient support program, TARPEYO Touchpoints™. This program offers services, assistance, and resources designed to help patients access treatment as easily as possible.

On December 15, 2021, Calliditas announced that FDA had granted accelerated approval to TARPEYO™ (budesonide) for the reduction of proteinuria in adult primary IgA Nephropathy patients at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. TARPEYO (developed under the project name NEFECON) was specifically designed for and is the first and only FDA-approved treatment in this disease. 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.

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The information was sent for publication, through the agency of the contact persons set out above, on January 28, 2022, at 08:00 a.m. CET.

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, TARPEYO, has been approved by the FDA as the first and only treatment indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression. Calliditas has also filed a marketing authorization application (MAA) with the European Medicines Agency (EMA) for this drug product. Additionally, Calliditas plans to initiate clinical trials with NOX inhibitor

product candidates 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).

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.
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. Through their anti-inflammatory and immunosuppressive effects at the glucocorticoid receptor, corticosteroids can modulate B-cell numbers and activity. It has not been established to what extent TARPEYO's efficacy is mediated via local effects in the ileum vs systemic effects.

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 Full Prescribing Information (link below), 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.

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 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, 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.

[1] 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