Stockholm, Sweden **December 20, 2023**

Calliditas Therapeutics announces full FDA approval of TARPEYO®, the only FDA-approved treatment for IgA nephropathy to significantly reduce the loss of kidney function

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas"), today announced that the U.S. Food and Drug Administration (FDA) has approved TARPEYO (budesonide) delayed release capsules to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. TARPEYO was first approved in December 2021 under accelerated approval, based on the surrogate marker of proteinuria. Marking a significant milestone, TARPEYO is now the first fully FDA-approved treatment for IgAN based on a measure of kidney function.

- TARPEYO (investigational name NEFECON) is the only FDA-approved treatment for IgAN to significantly reduce the loss of kidney function.
- TARPEYO is now approved with a confirmed and statistically significant benefit over placebo ($p<0.0001$) in estimated glomerular filtration rate (eGFR) over the two-year period that consisted of 9 months of treatment with TARPEYO plus optimized renin-angiotensin system inhibitor (RASi) or placebo and optimized RASi and 15 months of follow-up off study drug.
- At 2 years, there was a 6.11 mL/min/1.73 m^2 decline in eGFR in the TARPEYO group compared with a 12.0 mL/min/1.73 m^2 decline in the placebo group ($p<0.0001$), representing 50% less deterioration of kidney function in TARPEYO-treated patients compared to placebo-treated patients over the 2-year period.
- TARPEYO is a B-cell immunomodulator designed to target a source of the disease and reduce the production of pathogenic galactose-deficient IgA1 antibodies, which cause IgAN.[1-3]
- Significant proteinuria reduction achieved with TARPEYO plus RASi at 9 months was durable and maintained throughout the 15-month off-drug period.
- The FDA approval is for adults with primary IgAN who are at risk of disease progression, irrespective of proteinuria levels.

"The evidence of sustained reductions in proteinuria and a clinically significant reduction in the loss of eGFR, which can help slow the progression towards dialysis or transplant care, highlights the potential of TARPEYO as a disease-modifying agent in IgAN," said Richard Lafayette, MD, FACP, Stanford Healthcare. "TARPEYO provides physicians and patients an effective treatment option to help improve disease outcomes."

The approval is based on data from the Company's Phase 3 NefIgArd clinical trial, a randomized, double-blind, multicenter, study that assessed the efficacy and safety of TARPEYO dosed at 16 mg once daily versus placebo on a background of optimized RASi therapy in adult patients with primary IgAN.

"We are thrilled that adult IgAN patients at risk for progression in the United States can now have access to this pioneering treatment option that could help preserve their kidney function and, hence, impact the progression of their disease," said Renee Aguiar-Lucander, CEO of Calliditas. "This medicine was specifically developed to target an underlying cause of IgAN, and I would like to express my gratitude to

the Calliditas team, study investigators, and most importantly, the patients and caregivers who made this significant milestone possible. I am incredibly proud of the team's unwavering commitment to the goal of preventing end-stage renal disease in patients with this challenging rare disease."

TARPEYO was generally well-tolerated in the Phase 3 NefIgArd clinical trial. The most common adverse reactions (≥5%) in this study were peripheral edema, hypertension, muscle spasms, acne, headache, URT infection, face edema, weight increased, dyspepsia, dermatitis, arthralgia, and white blood cell count increased. Please see Important Safety Information below.

"This first-ever IgAN treatment to get a full approval based on kidney function represents a beacon of hope for the entire IgA nephropathy community and signifies a critical step forward in the battle against IgAN," said Bonnie Schneider, director and cofounder of the IgAN Foundation. "The foundation is elated and personally this is so rewarding and validating after a near 20-year journey since founding this volunteer-run organization to raise awareness and promote research for IgAN."

TARPEYO is available exclusively through Calliditas specialty pharmacy, Biologics by McKesson. To get started with TARPEYO, prescribers must fill out a TARPEYO Touchpoints® Enrollment Form, which serves as a prescription. This Enrollment Form will connect patients with all the benefits provided by TARPEYO Touchpoints®, including financial aid programs that can eliminate or reduce out-of-pocket costs, assistance from our team of care navigators, pharmacists, and nurse educators; and the convenience of at-home, next-day delivery. At Calliditas, we believe that the cost of treatment should never be a barrier to care. With TARPEYO Touchpoints®, 97% of patients taking TARPEYO have paid less than $10 per prescription, and 88% have paid nothing at all.

Indication

TARPEYO is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

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 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. Chickenpox 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 (e.g., 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 or cataracts, or with a family history of diabetes or glaucoma, or with any other condition where corticosteroids may have unwanted effects.

Adverse reactions: In clinical studies, the most common adverse reactions with TARPEYO (occurring in ≥5% of TARPEYO treated patients, and ≥2% higher than placebo) were peripheral edema (17%), hypertension (12%), muscle spasms (12%), acne (11%), headache (10%), upper respiratory tract infection (8%), face edema (8%), weight increased (7%), dyspepsia (7%), dermatitis (6%), arthralgia (6%), and white blood cell count increased (6%).

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

TARPEYO is an oral 4mg delayed release formulation of budesonide, 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. [1-3]

About the NeflgArd Study

NeflgArd was a global, 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 RASi therapy. Patients were randomized 1:1 to receive 16 mg/day oral capsules of TARPEYO or matching placebo for 9 months, followed by a 15-month observational follow-up period without the study drug.

The primary efficacy endpoint was time-weighted average of eGFR over 2 years. The time-weighted average of eGFR over 2 years showed a statistically significant treatment benefit with TARPEYO versus placebo (difference 5·05 mL/min per 1·73 m² [95% CI 3·24 to 7·38], p<0·0001).

The favorable effect of TARPEYO on eGFR was seen by Month 3 (the earliest assessment) and did not appear to increase in magnitude over two years. At the end of Year 2, there was a 5.9 mL/min/1.73 m^2 difference in the mean change from baseline in eGFR between TARPEYO and placebo (95% CI: 3.3 to 8.5 mL/min/1.73 m^2; p<0.0001). The effect on kidney function seen during the 9-month treatment period persisted following completion of treatment through the end of the study but the overall effect on the long-term rate of decline has not been established.

The most common adverse reactions with TARPEYO (occurring in ≥5% of TARPEYO treated patients and ≥2% higher than placebo) were peripheral edema (17%), hypertension (12%), muscle spasms (12%), acne (11%), headache (10%), upper respiratory tract infection (8%), face edema (8%), weight increase (7%), dyspepsia (7%), dermatitis (6%), arthralgia (6%), and white blood cell count increase (6%).

About Primary Immunoglobulin A Nephropathy

Primary immunoglobulin A nephropathy (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.[2,4] 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 the late teens and late 30s.[2,5]

For further information, please contact:

Åsa Hillsten, Head of IR and Sustainability, Calliditas

Tel.: +46 76 403 35 43, email: asa.hillsten@calliditas.com

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 contact person set out above, on December 20, 2023 at 22:15 p.m. CET.

About Calliditas

Calliditas Therapeutics is a biopharma company headquartered in Stockholm, Sweden, focused on identifying, developing, and commercializing novel treatments in orphan indications with significant unmet medical needs.

Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT).

Visit 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. 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. TARPEYO. Prescribing Information. Calliditas Therapeutics AB; 2023.

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4. Barratt J, Feehally J. IgA nephropathy. *J Am Soc Nephrol*. 2005;16(7):2088-2097. https://doi.org/10.1681/ASN.2005020134

5. Jarrick S, Lundberg S, Welander A, et al. Mortality in IgA nephropathy: a nationwide population-based cohort study. *J Am Soc Nephrol*. 2019;30(5):866-876. https://doi.org/10.1681/ASN.2018101017