Stockholm, Sweden **May 15, 2024**

Calliditas Therapeutics to Present Data at ERA 2024 May 23 – 26 in Stockholm

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas"), today announced upcoming data presentations and a sponsored symposium at the 61st European Renal Association (ERA) Congress, in Stockholm, Sweden on May 23 – 26, 2024.

Data presentations will include an efficacy analysis of Nefecon (TARPEYO® (budesonide) delayed release capsules)) in primary immunoglobulin A nephropathy (IgAN) as well as a real-world analysis of the challenges associated with the use of systemic glucocorticoids (SGC) in IgAN.

"We are delighted to participate in ERA and look forward to engaging with the leaders in the renal space," said Richard Philipson, Chief Medical Officer at Calliditas. "We are especially excited to be in Stockholm, where Calliditas is headquartered and where we developed the first treatment specifically designed for IgA nephropathy, to present analyses that highlight the continued opportunity for our treatment to address the significant unmet need in this rare disease."

The presentation and symposium details are below. Following the meeting, they will be available on the Presentations and Publications page on Calliditas' corporate website.

Presentation Details:

Title: "Matching-adjusted indirect comparison of eGFR in patients with immunoglobulin A nephropathy treated with Nefecon (TRF budesonide) or sparsentan"
Oral Poster Presentation: 501129
Date and Time: May 25 3:15-4:30 CET
Location: Focused Oral Room 3

Title: "Real-world challenges associated with the use of systemic glucocorticoids in a US IgAN cohort"
Poster Number: 2533
Date and Time: May 26 8:54-9:06 CET
Location: A5

Symposium Details:

Title: Clinical Markers in IgA Nephropathy: Is All Proteinuria the Same?
Date and Time: Saturday, May 25: 10:15 - 11:15 am (Room A2+A3)
Moderator: Prof. Jonathan Barratt, Renal Medicine at Leicester University.
Panel: Shikha Wadhwani, MD, MS, FASN Northwestern University; Richard Lafayette, M.D., F.A.C.P., Stanford Healthcare

For more information, visit the ERA 2024 website here.

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.

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.

For further information, please contact:

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The information was sent for publication, through the agency of the contact persons set out above, on May 15, 2024, at 14.00 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' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT). Visit Calliditas.com for further information.