

Stockholm, Sweden

January 7, 2024

Calliditas Therapeutics appoints Maria Törnsén as President North America

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”), a commercial biopharma company focused on rare diseases today announced that Maria Törnsén has been appointed to the position of President North America. Ms Törnsén will be responsible for all US based operations and will report to the CEO.

Maria Törnsén has broad commercial leadership experience having spent more than 20 years in the biopharma industry in senior commercial roles. Most recently Ms Törnsén held the position of Chief Commercial Officer at Passage Bio, prior to which she was SVP General Manager US at Sarepta Therapeutics. Prior to joining Sarepta she served as VP Global Therapeutic Area Head at Sanofi Genzyme and held several senior commercial roles at Shire including VP Head of US Sales. Ms Törnsén will replace Mr Andrew Udell, who has held the position since 2020.

“We are pleased to welcome Ms Törnsén to the executive management team as President of our US operations. She brings invaluable experience from building commercial organisations, driving growth and profitability in the area of rare diseases, which will be critical as we target the next step in our development.” said CEO Renée Aguiar-Lucander. “I also want to thank Mr Udell for his valuable contribution to the build-up of the US organisation and its early commercial success.”

“I am delighted to join Calliditas at this exciting time in the company’s history, with the recent full FDA approval of TARPEYO® and an innovative late-stage pipeline in rare diseases. I look forward to working with the Calliditas team to continue advancing the TARPEYO® launch and develop our capabilities to support further growth.” said Maria Törnsén.

Calliditas received full FDA approval of TARPEYO®(budesonide) delayed release capsules, a targeted treatment to reduce the loss of kidney function in patients with primary IgA nephropathy (IgAN) at risk of disease progression on December 20, 2023; the product has been granted conditional approval in Europe and China and is being commercialized by partners under the brand names of Kinpeygo and Nefecon, respectively. Calliditas is targeting top line read out of several Phase 2 clinical trials with setanaxib, its lead product candidate from its proprietary and novel NOX platform, in 2024.

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas
Tel.: +46 76 403 35 43, Email: asa.hillsten@calliditas.com

The information was sent for publication, through the agency of the contact persons set out above, on January 7, 2024 at 5:00 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.

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 $\geq 5\%$ of TARPEYO treated patients, and $\geq 2\%$ 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](#)

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 the development of Calliditas' pipeline. 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, clinical trials, intellectual property of the NEFECON franchise globally, competition from other companies, pipeline development, 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.