

Calliditas Therapeutics appoints Frank Bringstrup as VP Regulatory Affairs

Calliditas Therapeutics AB (publ) (NASDAQ Stockholm: CALTX) (“Calliditas”) today announced the appointment of Dr. Frank Bringstrup as Vice President Regulatory Affairs effective February 1, 2019. As a member of the Management Team, Frank will have a leading role in the regulatory discussions and approval process of the company’s pivotal clinical phase 3 study NEFIGARD in patients with IgA nephropathy (IgAN).

“I am delighted to welcome Frank to the team at this exciting stage in the company’s development. The combination of his strong experience in regulatory affairs, not only with the FDA but on a broad international basis with a proven track record and experience from orphan drug development and bringing products to market will play a key role as we progress development of Nefecon through phase 3 clinical trials”, said Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

Dr. Bringstrup brings over 17 years’ experience in the pharmaceutical industry in regulatory affairs and health authority interactions. He worked in various positions at Novo Nordisk A/S, most recently as their Senior Global Regulatory Lead. During his time at Novo Nordisk, he led the strategic regulatory input for the orphan drug NovoEight® all the way from phase 1 through phase 3 with five parallel MAAs and NDAs and five major approvals gained in a 15-month period.

Dr. Bringstrup has a wealth of experience of Regulatory Affairs in the US, EU, Japanese and international markets, and was, among other things, responsible for overseeing the lifecycle development for new indications for the orphan drug NovoSeven®, a recombinant human coagulation Factor VIIa (rFVIIa), intended for promoting hemostasis by activating the extrinsic pathway of the coagulation cascade.

“I am excited to take on this role at Calliditas. With the phase 3 trial of Nefecon well underway, this is a pivotal time for the company. Currently, there are no approved treatments for IgA Nephropathy, and Nefecon has the potential to be a disease-modifying treatment for patients suffering from this chronic autoimmune disease. I am delighted to be working with this dynamic team to progress the development of Nefecon through to market”, said Frank Bringstrup.

Dr. Bringstrup originally qualified as a Medical Doctor from the University of Copenhagen and started his professional career first in clinical practice as a physician, next as Frederiksborg County Medical Advisor. He has a Diploma in Managing Medical Product Innovation (MMPI) from Copenhagen Business School, a Diploma in Business Administration from Warwick University, a Post-Graduate Specialist Course in Public Health Medicine from the National Board of Health, Denmark.

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About Calliditas

Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden, focused on developing high quality pharmaceutical products for patients with a significant unmet medical need in niche indications, in which the Company can partially or completely participate in the commercialization efforts. The Company is focused on the development and commercialization of the product candidate Nefecon, a unique formulation optimized to combine a time lag effect with a concentrated release of the active substance budesonide, within a designated target area. This patented, locally acting formulation is intended for treatment of patients with the inflammatory renal disease IgA nephropathy. Calliditas Therapeutics aims to take Nefecon through a global Phase 3 study to commercialization. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit www.calliditas.com for further information.

About Nefecon

Nefecon is a potential treatment for patients with IgAN at risk of developing ESRD. It is a proprietary oral formulation of budesonide, designed to deliver budesonide to the ileum where the so-called Peyer's patches, which harbor the majority of B-cells producing IgA antibodies, are found. By delivering budesonide locally instead of systemically, Nefecon greatly reduces the side-effect burden observed with high dose steroid treatment while optimizing the effective dose level of the drug where it is required. Budesonide has been used to treat patients with asthma, inflammatory bowel disease and allergic rhinitis for over 35 years. It is rapidly degraded soon after entering the circulatory system, making it an ideal basis for drugs such as Nefecon because local delivery to disease tissue minimizes the systemic effects seen with other corticosteroids. Nefecon has been granted orphan drug designation for IgAN by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About IgA Nephropathy (IgAN)

IgA nephropathy (IgAN) – also known as Berger's disease – is the most common form of glomerulonephritis, a chronic inflammatory condition of the kidney, in the Western world. IgAN is a serious autoimmune, progressive disease that leads to decreasing kidney function over the course of 10 to 20 years. Up to 50 percent of patients diagnosed with IgAN will progress to end-stage renal disease (ESRD), a disease state requiring dialysis or kidney transplant for survival due to insufficient kidney function within 20 years. IgAN is an orphan disease, designated as an orphan indication in both the US and Europe. IgAN affects approximately 130,000–150,000 people in the US and about 250,000 people in Europe. Today, there are no approved treatments for IgAN. Today's standard of care treatment regimens entails primarily established, generic drugs such as blood pressure lowering agents to alleviate symptoms, complemented by off-label use of systemic corticosteroids.