

Calliditas Therapeutics appoints Andrew Udell to VP Commercial, North America

Calliditas Therapeutics AB (publ) (NASDAQ Stockholm: CALTX) (“Calliditas”) today announced the appointment of Andrew Udell as Vice President, United States Commercial, effective February 1, 2019. Mr. Udell will be part of the management team and brings over two decades of commercial and marketing experience in the biotechnology and pharmaceutical industries.

“Andrew truly brings deep expertise in commercial planning, strategy development and execution, and we are extremely pleased to welcome him to Calliditas,” said Renée Aguiar-Lucander, Chief Executive Officer of Calliditas Therapeutics. “His successful track record of transitioning research and development phase organizations to commercial stage companies will be a key asset as we build out our US commercial presence in advance of launching Nefecon in IgA nephropathy (IgAN). With patient recruitment ongoing in our pivotal Phase 3 study of Nefecon, we continue to lead the development efforts for an effective therapeutic treatment with disease modifying potential for patients with IgAN, a disease with no currently approved medications.”

Prior to joining Calliditas, Mr. Udell served as Vice President of Commercial for North America at Neuroderm Ltd., until to the Company’s \$1.1bn acquisition by Mitsubishi Tanabe Pharma. He previously served in commercial leadership roles in the biotech industry, including at Intrexon Corporation as Vice President, Marketing and Communications, and as Vice President of Marketing at Clinical Data Inc., where he was responsible for the US commercial launch of the company’s flagship product, Viibryd™, a novel antidepressant.

Mr. Udell also spent a decade working in several sales and marketing leadership roles at Purdue Pharma, ultimately leading a cross-functional team for a \$2 billion pain medication franchise. Mr. Udell earned his BSc from Lehigh University and an MBA from the University of Connecticut.

“As demonstrated by compelling, placebo-controlled, Phase 2b clinical data, Nefecon has the potential to address a significant unmet medical need for patients with IgAN,” said Andrew Udell. “I look forward to working with the team at Calliditas to design and execute a successful US commercial strategy for this promising treatment option.”

For further information, please contact:

Mikael Widell, Head of Communications

Email: mikael.widell@calliditas.com

Telephone: +46 703 11 99 60

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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 the 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 proprietary oral formulation of budesonide being developed as a potential treatment for patients with IgAN at risk of developing end stage renal disease (ESRD). Nefecon is designed to deliver budesonide to the ileum, the location of Peyer's patches, which harbor the majority of B-cells producing IgA antibodies. By delivering budesonide locally to disease tissue and degrading rapidly in the circulatory system, Nefecon optimizes the effective dose level of the drug where it is required and greatly reduces the side-effect burden associated with systemic high dose steroid treatment. Budesonide has been used to treat patients with asthma, inflammatory bowel disease and allergic rhinitis for over 35 years. Nefecon has been granted Orphan Drug Designation for IgAN by the U.S. Food and Drug Administration and the European Medicines Agency.

About IgA Nephropathy (IgAN)

Immunoglobulin A 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 progressive autoimmune disease that leads to decreasing kidney function over the course of 10 to 20 years. Up to 50% of patients diagnosed with IgAN progress to ESRD, a disease state requiring dialysis or kidney transplant for survival due to insufficient kidney function, within 20 years. IgAN is an orphan designated indication in the U.S. and Europe, affecting approximately 130,000–150,000 people in the U.S. and approximately 250,000 people in Europe. There are no approved treatments for IgAN. Today's standard of care treatment regimens entail primarily established, generic drugs such as blood pressure lowering agents to alleviate symptoms, complemented by off-label use of systemic corticosteroids.