

Stockholm, Sweden, and Shanghai, China



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Calliditas Therapeutics and Everest Medicines Enter into an Agreement to Develop and Commercialize Nefecon for IgA Nephropathy in Greater China and Singapore

Deal valued at a total of USD 121M plus royalty payments

Calliditas Therapeutics AB ("Calliditas") and Everest Medicines II Limited ("Everest Medicines") announced today that they have entered into a license agreement to develop and commercialize Calliditas' leading drug candidate Nefecon in Greater China and Singapore for the chronic autoimmune kidney disease IgA Nephropathy (IgAN).

Under the terms of the agreement, Calliditas will receive an initial upfront payment of 15M USD at signing of the agreement, as well as future payments linked to pre-defined development, regulatory and commercialization milestones up to an additional 106M USD, including an option worth up to 20M USD for the development of Nefecon in other potential indications. Everest will also pay typical royalties on net sales.

Calliditas is currently running a pivotal, global Phase 3 clinical trial with Nefecon for the treatment of patients with IgAN. The agreement gives Everest Medicines exclusive rights to develop and commercialize Nefecon in China, Hong Kong, Macau, Taiwan and Singapore and may, depending on the outcome of consultation with the relevant regulatory authorities, lead to the inclusion of Chinese study centers in the ongoing pivotal study, <u>NefIgArd</u>, with the result of achieving registration approval for the Chinese market on an accelerated basis. Following potential registration approvals, Everest will be responsible for the commercialization of Nefecon in the relevant territories.

"We are excited to be entering into this partnership with Everest Medicines to expand Nefecon's market reach to China, where there is a significant unmet medical need for this large patient population. We look forward to working in close collaboration with Everest Medicines to bring the innovative approach of Nefecon, which has shown great promise in our large Phase 2b study, to IgAN patients as rapidly as possible. Everest Medicines offers a unique combination of strong expertise in the clinical development and regulatory arena, with an innovative biopharma approach for this market," said Renée Aguiar-Lucander, CEO of Calliditas Therapeutics AB.

While IgAN is an orphan disease in the US and Europe, the prevalence is much higher in China, where IgAN is the most common primary glomerulonephritis and accounts for about 40% of primary glomerular diseases. China is the world's largest market in terms of the number of IgAN patients which extracts a significant economic and social impact.

"We look forward to partnering with Calliditas to develop and commercialize Nefecon as a potential novel therapy for the treatment of IgAN," said Ian Woo, President and Chief Financial Officer of Everest Medicines. "Calliditas' strong foundation of clinical development of Nefecon, coupled with Everest's local clinical and regulatory expertise lays the groundwork for expediting the development of this promising therapeutic candidate as a potential treatment option for patients in Greater China and Singapore suffering from IgAN."





The first 200 randomized patients in the ongoing pivotal NefIgArd study will form the basis for topline data readout expected to occur during the second half of 2020, following which Calliditas will submit the applications for accelerated/conditional regulatory approval to the US Food and Drug Administration and the European Medicines Agency respectively.

Torreya acted as exclusive financial advisor to Calliditas on the transaction.

The information in the press release is such that Calliditas Therapeutics AB (publ) is required to disclose pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, at 8:00 am CET on June 10, 2019

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About Calliditas Therapeutics

Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden. It is 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 (IgAN). Calliditas Therapeutics is running a global Phase 3 study within IgAN





and plans to commercialize Nefecon in the US. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit <u>www.calliditas.se</u> for further information.

About Everest Medicines

Everest is a CBC Group-backed biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products that address critical unmet medical needs for patients in Greater China and other Asian markets. The management team of Everest has deep expertise and an extensive track record of high-quality clinical development, regulatory affairs, CMC, business development and operations both in China and with leading global pharmaceutical companies. For more information, please visit its website at <u>www.everestmedicines.com</u>.

About CBC Group

CBC Group, formerly known as C-Bridge Capital, is a healthcare dedicated private equity firm, focused on growth and late stage, early stage and incubation opportunities across the healthcare industry. CBC Group is committed to supporting the commercialization of cutting-edge technologies and companies that fulfil unmet medical needs, thus continuously improving the standard and quality of care for patients. For more information, please visit http://www.cbridgecap.com/#/indexEng.

About Nefecon

Nefecon is a potential treatment for patients with IgAN at risk of developing end-stage renal disease (ESRD). It is a proprietary oral formulation of budesonide, designed to deliver the acive ingredient to the ileum where the Peyer's patches, which harbor the majority of B-cells producing IgA antibodies, are found. By delivering a potent drug locally instead of systemically, Nefecon greatly reduces the side-effect burden observed with for example high dose steroid treatment while optimizing the effective dose level of the drug where it is required. Budesonide has been used to treat patients locally with asthma for over 20 years. It has low bioavailability and as such is rapidly degraded soon after entering the circulatory system, making it an ideal basis for drugs such as Nefecon because of the need for local delivery to disease tissue. 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. 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 ESRD, a disease state requiring dialysis or kidney transplant for survival due to insufficient kidney function. IgAN is designated as an orphan indication in both the US and Europe and affects approximately 130,000–150,000 people in the US, about 200,000 people in Europe. Today, there are no approved treatments for IgAN. Today's recommended standard of care treatment regimen entails primarily established, generic drugs such as blood pressure lowering agents to alleviate symptoms.