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ASIA EDITION

Calliditas Therapeutics to commercialize autoimmune drug in China, Singapore

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

Sweden based Calliditas Therapeutics AB ("Calliditas") and US based Everest Medicines II Limited ("Everest Medicines") announced 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, NefIgArd, 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.

Renée Aguiar-Lucander, CEO of Calliditas Therapeutics AB said, "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."

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.

Ian Woo, President and Chief Financial Officer of Everest Medicines said, "We look forward to partnering with Calliditas to develop and commercialize Nefecon as a potential novel therapy for the treatment of IgAN. 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.