

## **China IND approval triggers \$5 million milestone payment from Everest Medicines**

**Calliditas Therapeutics AB (publ) (“Calliditas”) today announced that a \$5 million milestone payment from its partner Everest Medicines II Limited (“Everest Medicines”) has been triggered as per the licensing agreement under which Everest is to develop and commercialize Calliditas’ leading drug candidate Nefecon in Greater China and Singapore.**

The National Medical Products Administration (NMPA, formerly known as CFDA) has approved Everest Medicine’s IND (Investigational New Drug application) for Nefecon in China, an important step toward allowing Chinese clinical sites to recruit patients for the ongoing NeflgArd global Phase 3 trial. This is the first of a set of pre-defined development, regulatory and commercialization milestones of up to \$106 million under the license agreement between Calliditas and Everest Medicines, announced in June 2019, giving Everest Medicines exclusive rights to develop and commercialize Nefecon in China, Hong Kong, Macau, Taiwan and Singapore.

This approval will allow Everest Medicines to start working towards including China based clinical sites to the ongoing global Phase 3 trial, NeflgArd, thereby contributing to the recruitment of the 160 patients expected to be randomized during 2020 into Part B of the trial.

“This is truly exciting news. To have the NMPA approve the IND 6 months after entry into the license deal, thereby enabling a rapid route to market in China is very positive and reflects the good collaboration between the parties as well as the strong knowledgebase and speed of execution by our partner Everest Medicines. We look forward to continuing our collaboration with Everest Medicines in order to bring Nefecon to patients and address the significant unmet medical need in China.” 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, accounting 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.

Calliditas currently is conducting NeflgArd, a pivotal, global Phase 3 clinical trial with Nefecon for the treatment of patients with IgAN. The first 200 randomized patients in the ongoing study will form the basis for topline data readout expected to occur in Q4 of 2020. Based on positive results, Calliditas will submit an application for accelerated regulatory approval to the U.S. Food and Drug Administration and an application for conditional approval to the European Medicines Agency.

*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 11:40 CET on December 17, 2019.*

**For further information, please contact:**

Renée Aguiar-Lucander, CEO, Calliditas  
Email: renee.lucander@calliditas.com  
Telephone: +46 722 52 10 06

Mikael Widell, Head of Communications  
Email: mikael.widell@calliditas.com  
Telephone: +46 703 11 99 60

**About Calliditas**

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 aims to commercialize Nefecon in the US. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit [www.calliditas.com](http://www.calliditas.com) for further information.