

## **First patient in China enrolled in clinical phase 3 study NeflgArd with lead candidate Nefecon**

**Calliditas Therapeutics AB (publ) ("Calliditas") today announced that the first patient in China has been randomized into confirmatory part of the NeflgArd Phase 3 trial by its partner, Everest Medicines.**

Following IND approval by the NMPA in December of 2019 and subsequent approval by Human Genetic Resources Administration of China (HGRAC), the first patient in China has now been randomized in the Phase 3 NeflgArd trial. The first patient in NeflgArd was randomized by Calliditas in November 2018, and in December 2019 Calliditas announced the full recruitment of the 200 patients required for regulatory submission (Part A). Topline data for these 200 subjects is targeted for Q4 of 2020, which subject to positive data will form the basis for regulatory approval and market access in the US and Europe. The study has continued to recruit an additional 160 patients in order to complete the confirmatory part (Part B) of the trial, which relates to the validation of the surrogate marker, proteinuria. Everest Medicines is contributing to the recruitment of these 160 patients, based on the roll-out across centers in China.

"We are very pleased to now have the first patient from mainland China enrolled into the NeflgArd trial. As this disease represents a significant unmet need in Asia, we are excited that Everest Medicines have achieved this milestone, which supports the goal of completing recruitment before the end of the year," said Renée Aguiar-Lucander, CEO of Calliditas Therapeutics.

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*The information was sent for publication, through the agency of the contact persons set out above, on September 8, 2020 at 08:00 a.m. CET.*

**About Calliditas**

Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. Calliditas is running a global Phase 3 study within IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit [www.calliditas.com](http://www.calliditas.com) for further information.

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events

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