

Positive opinion received from EMA Paediatric Committee on the Paediatric Investigation Plan for Nefecon for the treatment of IgAN

Calliditas Therapeutics AB (publ) (“Calliditas”) today announced that the EMA Paediatric Committee (PDCO) has adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy (IgAN).

With successful completion of the agreed PIP, Nefecon would be eligible for up to an additional two years of marketing exclusivity in the EU, on top of the ten-year EU market exclusivity after market approval.

As part of the regulatory process for the registration of new medicines in Europe, pharmaceutical companies are required to provide a PIP outlining their strategy for investigation of the new medicinal product in the paediatric population. An approved PIP is a prerequisite for filing a Marketing Authorisation Application (MAA) for a new medicinal product in the EU.

Acceptance of this Paediatric Investigation Plan (PIP) paves the way for the potential submission of a MAA in Europe following completion of Part A of the ongoing phase 3 trial NeflgArd.

“We are pleased to announce this important regulatory milestone. The approval of the PIP provides Calliditas Therapeutics with a clear path for registration of Nefecon for the treatment of a significant portion of paediatric patients with IgAN. We look forward to continuing to work with EMA and PDCO to bring this important therapy to the European market as soon as possible,” said Renée Aguiar-Lucander, Chief Executive Officer.

The information was submitted for publication, through the agency of the contact person set out below, at 08:00 CET on January 22, 2020.

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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 for further information.