

## **Calliditas provides a corporate business update in the context of the Covid-19 pandemic**

**Calliditas Therapeutics AB (publ) (“Calliditas”) today provided an update on its business activities and financial position as well as the initiatives announced to continue to build its organization amid the evolving COVID-19 pandemic, all while promoting the continuity of the development of its late stage R&D portfolio.**

### R&D portfolio update

To date, Calliditas does not anticipate that the Covid-19 pandemic will significantly impact the ongoing clinical activities related to NeflgArd, the company’s Phase 3 pivotal trial in IgA nephropathy (IgAN). Due to the facts that the Part A of the study was fully recruited in December 2019, that Nefecon is an oral formulation which patients are able to take at home, and that it is global and requires limited interaction among participants and the healthcare system, the overall impact of the Covid-19 pandemic on the study has been very limited to date, and our estimated timeline for a read out of Part A in the fourth quarter of 2020 currently remains intact. With sites in 19 countries participating in the trial, there are several geographies facing challenging situations in their healthcare systems, but the Calliditas team, in close cooperation with national coordinators, primary investigators, study nurses and our contract research organization (CRO), believes it has been able to put in place effective measures designed to ensure patient safety and preserve trial data integrity, as well as communicated timelines.

There are however still uncertainties with regard to the continued development of Covid-19 and its implications, which is why Calliditas will continue to assess the situation and seek to put in place relevant mitigating measures where necessary over time. Calliditas remains committed to leverage each and every part of the extended organization’s collective expertise with the goal of ensuring that the trial is successfully completed and thereby supporting our efforts to provide an approved drug for patients with IgAN.

Regarding initiation of new studies related to pipeline indications, or Nefecon related open label studies currently slated to start later in the year, it remains unclear as to what extent these will be impacted by Covid-19. However, the company is cautiously assuming that there might be delays with respect to the initiation of these additional studies.

In December 2019, the company announced the full recruitment of all 200 patients required for Part A of the company’s pivotal Phase 3 trial NeflgArd. Top line readout of Part A of the trial is still on track for Q4 2020, and Calliditas aims to have the necessary data on hand to file for accelerated or conditional, as applicable, FDA and EMA approval in the first half of 2021.

The NeflgArd trial is continuing to recruit an additional 160 patients during 2020. Recruitment in the first quarter was above plan, but in light of the ongoing pandemic, the company is expecting a reduction of recruitment rates over the next several months. Nevertheless, based on existing patient numbers in combination with significantly enhanced recent activities in China related to their complementary recruitment activities, we continue to expect to report data from Part B readout in 2022.

### Organizational update

Calliditas has followed the recommendations of domestic public health authorities, calling for the ability of staff to work from home, if possible. We have supported and implemented a work from home policy for our employees, as per guidance, while the office remains open for ongoing necessary activities. Considering the significant amount of activities that have historically been conducted across digital platforms, this has not to

date resulted in any significant impact on day-to-day activities of the company and we expect this to continue to be the case under the prevailing restrictions.

We have actively continued to build on our existing expertise and skills across the organization with a particular focus on the US. Over the last couple of months, we have added a Director of Medical Affairs in the US, a VP of Market Access in the US and recruited a CMO to take over from our Head of Medical Affairs who has held the position of acting CMO since December 2019. We have also made, and will continue to make, complementary additions across the organization in our endeavor to be fully prepared for commercialization in the US, on the basis that Nefecon will be approved. As of today, no employees have been infected with Covid-19 to the knowledge of the company.

#### Financial update

At December 31, 2019, cash and cash equivalents amounted to SEK 753.5 million, and Calliditas confirms its cash runway well into H2 2021, significantly beyond the next anticipated key clinical milestone, expected in the fourth quarter of 2020.

“Calliditas has to date managed to successfully address the most critical potential implications of the Covid-19 outbreak during this phase with very limited impact on the NeflgArd study. However, as the outbreak continues to develop, we will continue to monitor the situation closely in order to anticipate and address any potential deviations which might impact the clinical trial. Our focus is obviously on taking appropriate measures to ensure the safety of the participants in our clinical trials and preserve the integrity and quality of ongoing clinical activities,” said Renée Aguiar-Lucander, CEO of Calliditas.

Aguiar-Lucander also noted, “We will continue to closely monitor, assess and respond to the situation as needed and as it evolves over time, and we will continue to work closely with our CRO, trial sites and investigators to critically review local conditions and will communicate further on the situation when and if appropriate.”

#### **For further information, please contact:**

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

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

*The information was sent for publication, through the agency of the contact persons set out above, on April 27, 2020 at 08:00 a.m. CET.*

#### **About Calliditas**

Calliditas Therapeutics AB is a specialty pharmaceutical company headquartered 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 two-step 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.