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IDOGEN AB

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Idogen provides update on timelines for the development of the tolerogenic cell therapy IDO 8

Idogen AB ("Idogen") is today announcing that the company is postponing the planned start of the first clinical trial of the tolerogenic cell therapy IDO 8 from the first to the second half of 2021. This is due to temporary limitations in capacity at the manufacturing partner Radboud University Medical Center as a result of the COVID-19 pandemic. Following the successful establishment and scaling up of manufacturing during the spring, work is now in progress to document the processes prior to an application for the commencement of clinical trials in patients with haemophilia A. The company expects to file the application with the Swedish Medical Products Agency towards the end of the first half of 2021.

During spring 2020, the establishment and scaling up was successfully carried out of the manufacturing process for Idogen's unique cell therapy products at the company's GMP-certified partner, Radboud University Medical Center in the Netherlands. Extensive work is currently in progress aimed at documenting and qualifying the processes prior to the planned first clinical trial of IDO 8. However, these efforts were impacted by capacity limitations arising as a result of the ongoing COVID-19 pandemic and the unit's close link to hospital activities. Idogen's manufacturing partner has, however, recently been able to once again increase its capacity and is now striving to minimise the incurred delay, without compromising on the high standards imposed on quality.

Alongside of this production work, Idogen is continuing its interaction with the Swedish Medical Products Agency to ensure that its application to start clinical studies is in line with the Agency's requirements. Idogen estimates that such an application can be filed towards the end of the first half of 2021. The recently announced recruitment of Idogen's new Chief Regulatory Officer, Vicki Venizelos, who has many years of experience within regulatory affairs in general, and within cell therapy in particular, will strengthen the company in this important work.

"It is satisfying that Idogens manufacturing partner has succeeded, despite its limited capacity during the COVID-19 pandemic, to establish a successful production process for our cell therapy. We have chosen to make a slight adjustment to the timelines of the project to ensure that we maintain the high standards imposed on quality in the remaining development work. The capacity-related delay at Radboud University Medical Center results in a delayed start to the clinical study, but we see good opportunities to shorten the time for patient recruitment by using several trial centers that operate in parallel. Our previous assessment was that the clinical study can be completed in December 2022 and at present we see good opportunities to complete it during the first quarter of 2023, says Anders Karlsson, CEO of Idogen.

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Idogen (Nasdaq First North Growth Market: IDOGEN) develops tolerogenic cell therapies to prevent the patient's immune system from attacking biological agents, transplanted organs or the body's own cells or tissues. The company's most advanced project, IDO 8, is designed to restore the efficacy of haemophilia drugs in patients who have developed neutralising antibodies. The company's second project, IDO T, is being developed to prevent kidney transplant rejection. In a third programme, IDO AID, Idogen is focused on the treatment of autoimmune diseases. The treatment for all indications is based on the patient's own cells and is expected to have a favourable safety profile and long-lasting effect. The potential for a short-term treatment to yield a long-term effect is a major advantage in health economics for both patients and divisions providing care.