PRESS RELEASE
IDOGEN AB

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Idogen continues to optimize its production method prior to the start of the patient study with IDO 8

Idogen AB announces today that it has initiated new activities in order to maximize the effect of the tolerogenic cell therapy IDO 8 before the start of the first clinical study. The company has already succeeded in establishing a patentable process for the GMP-production of individually tailored treatments.

Åsa Schiött, CSO of Idogen: "Recently performed analyses show a potential to optimize the levels of the substance in cell therapy that the body should learn to recognize and tolerate. This in turn would increase the possibility of an improved treatment effect to benefit the patient". A clinical trial application (CTA) for the start of the planned clinical study on patients with antibodies to their treatment of hemophilia A is expected to be submitted to relevant authorities by the end of 2021. Subject to approval by the relevant health authorities, the study is expected to be initiated during the first quarter 2022, which is later than previously communicated.

Following a successful establishment and upscaling of the manufacturing process for Idogen's cell therapy products, extensive work has been carried out with the aim of documenting and qualifying production for the planned first clinical study of IDO 8. In parallel with this, the company has conducted customary discussions with the relevant health authorities, completed the study protocol and prepared its application for the start of studies. This application is ready to be submitted as soon as the now initiated activities to optimize the production process have been completed. All in all, it can be stated that the company has succeeded in minimizing most of the negative effects on the operations that the covid-19 pandemic caused. The start of the study, which was previously expected to take place at the turn of the year 2021/22, is now planned for the beginning of the second quarter of 2022.

Idogen's cell therapy is tailored for each individual patient in a GMP-certified laboratory at the company's partner Radboud University Medical Center in the Netherlands. The patentable treatment is based on a combination of dendritic cells harvested from the patient, a tolerance inducer and the substance that the body's immune system must learn to tolerate. For IDO 8, this substance consists of factor VIII, a vital drug for haemophilia A which in many patients is inactivated as a result of an unwanted immune reaction.

"We see good opportunities to further strengthen the effect of our cell therapy IDO 8, and thereby increase the patient benefit and value of our project in the longer term. It was therefore an easy decision to initiate the complementary activities, even if the schedule for the upcoming clinical study is thus shifted", says Anders Karlsson, CEO of Idogen.

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The English text is an unofficial translation of the original Swedish text. In case of any discrepancies between the Swedish text and the English translation, the Swedish text shall prevail.

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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 hemophilia 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.