PRESS RELEASE
IDOGEN AB

Corp. Reg. No. 556756-8521
Date: 02 December 2021

Idogen has successfully completed the optimization of the GMP manufacturing process for the first clinical study with its tolerogenic cell therapy IDO 8

Idogen AB announces today that it has successfully maximized the antigen levels in the cell therapy IDO 8 that the body should learn to recognize and tolerate. This is considered to be an important feature in order to obtain a good treatment effect. The IDO 8 treatment is aiming to create tolerance for ongoing substitution treatment with coagulation factor VIII, a vital drug for hemophilia (hemophilia A) which in many patients is inactivated as a result of undesired immune reactions. The company will shortly submit a clinical trial application to start the first study in patients. Subject to required regulatory approvals, the study is planned to start during the second quarter of 2022

A successful tech transfer and scale-up of the manufacturing process for Idogen's cell therapy has been followed by extensive work aimed at optimizing, documenting and qualifying the manufacturing process for the planned first clinical study. The company's manufacturing partner, Radboud University Medical Center (RUMC) in the Netherlands, a world-leading manufacturer of cell therapies, has now optimized and qualified the manufacturing process, achieving product properties equivalent to those generated when IDO 8 was manufactured in Idogen's own research laboratory. This has been achieved through an effective collaboration between RUMC and Idogen.

"IDO 8 has shown very promising properties in preclinical studies and it is a great success that we can now, in a reproducible way, manufacture this unique tolerogenic cell therapy on a larger scale in order to be able start of the clinical trial program. The IDO 8 project has thus taken another significant step forward and we look forward to contributing to Idogen's continued work to create a medical solution to the problem of neutralizing antibodies to coagulation factor VIII", comments Professor Jolanda de Vries, RUMC.

“The extensive optimization work carried out during the autumn has resulted in our cell therapy IDO 8 being upgraded in a way that we believe significantly increases the possibilities to obtain a good treatment effect. We will shortly submit our application to the Medical Products Agency for the first clinical study for IDO 8, which is planned to start during the second quarter of 2022", says Anders Karlsson, CEO of Idogen.

Idogen's cell therapy will now be tailored for each individual patient in a GMP-certified laboratory at the company's partner Radboud University Medical Center in the Netherlands. The proprietary treatment is based on patients own cells, differentiated into dendritic cells using Idogen’s unique tolerance inducers and the specific antigen that the body’s immune system must learn to tolerate.

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This constitutes information that Idogen AB is required to publish under the EU's Market Abuse Regulation. The information was submitted for publication through the above contact person on 02 December 2021 08:12 CET

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.

Idogen (Nasdaq First 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 tissue. The company's most advanced project, IDO 8, is designed to restore the efficacy of hemophilia drugs in patients who have developed neutralizing 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 favorable safety profile and long-lasting effect. The potential for a short-term treatment intervention to yield a long-term effect is a major advantage in health economics for both patients and divisions providing care. More information about Idogen is available via https://www.idogen.com