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Idogen's cell therapy product successfully produced by GMP-certified manufacturing partner

Idogen AB (Nasdaq First North Growth Market: IDOGEN) has today announced that the manufacturing process for the company's tolerogenic cell therapy has been successfully established at its collaboration partner Radboud University Medical Center in the Netherlands. The next step is to qualify the process for the submission of an application for commencement of the first clinical trial, which is expected to be able to start in H1 2021.

Idogen's tolerogenic cell therapy is based on dendritic cells, a type of white blood cell that plays a key role in the immune system's ability to differentiate the body's own molecules and tissues from foreign and potentially harmful substances. The company's most advanced project, IDO 8, is designed to restore the efficacy of hemophilia A drugs in patients who have developed drug-neutralizing antibodies. Idogen is also pursuing the IDO T project to prevent kidney transplant rejection and IDO AID to improve treatment of rare autoimmune diseases.

Idogen has successfully transferred an internally developed method for manufacturing its cell therapy products to Radboud University Medical Center (RUMC). RUMC has successfully reproduced Idogen's data and carried out bridging tests that allow the qualification of the manufacturing process to be performed according to GMP-standard. This enables production of cell therapy products ahead of forthcoming clinical trials and planned future commercialization. Furthermore, RUMC has shown that the product can be frozen while maintaining its therapeutic functionality, thereby facilitating logistics in connection with clinical application.

"It is widely known that the establishment of scalable production of cell therapy products is a major challenge, so we are therefore very pleased about the significant milestones we can announce today. We have now taken yet another important step on the path to the first clinical trial of IDO 8, which is expected to commence in the first half of 2021," says Hanne Risager Romedahl, Chief Scientific Officer at 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.

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 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

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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.