

PRESS RELEASE

IDOGEN AB



Org nr. 556756-8521

Date: 11th of May, 2017

Tolerogenic vaccine for kidney transplantation to be next therapeutic area for Idogen

Idogen AB ("Idogen") today announces that the company has decided that solid organ transplantation will be its next therapeutic area. The company has adopted a progressive development strategy in which a tolerogenic vaccine for kidney transplantation will be developed in parallel with the first tolerogenic vaccine for the treatment of inhibiting anti-factor VIII antibodies in hemophilia A. The development work with a tolerogenic vaccine for kidney transplantation has now commenced with the intention to initiate the first clinical study in 2019.

Currently, following transplantation, patients are given lifelong treatment with drugs that heavily suppress the immune system, which has negative consequences in terms of increased risk of serious infections and cancer. Idogen sees an opportunity with its treatment method to improve graft survival and to reduce the need for immunosuppressive drugs. Idogen's second therapy area will therefore be a tolerogenic vaccine to prevent transplant rejection, primarily kidney transplantation. The development work is being conducted with the intention of initiating a Phase I/IIa study within kidney transplantation in 2019.

"Based on the three significant advances we have achieved in the past year with successful proof-of-concept in a model of hemophilia, results showing that we can influence parts of the human immune system in test tube experiments and our initiated transfer of the method to a GMP-customized process, we have great confidence in our technology. We have therefore decided on a more progressive development program with parallel development of tolerogenic vaccines within two different important therapeutic areas with need for a novel treatment regimen.", CEO Lars Hedbys comments.

Idogen is developing a platform technology that can be used to treat a large number of diseases and conditions in the fields of inhibitor antibodies to biological drugs, autoimmune diseases and post-transplant rejection. The same method currently being developed for hemophilia A can be used in additional therapeutic areas with only a minor adjustment of the technology.

Kidney transplantation

Kidney transplantation is the most common type of organ transplant and globally, almost 80,000 kidney transplants are carried out each year, of which about 20,000 takes place in Europe¹. The largest and most serious complication is if the recipient's immune system attacks, destroys and rejects the donated organ. To prevent this, the transplanted patients, with few exceptions, are given life-long treatment with a combination of drugs that inhibit the immune system. Although the proportion of patients that are able to keep a functioning transplanted kidney in the first year has increased over the last decades, there has been no improvement in the long-term graft survival². The immunosuppressive treatment also poses a risk of serious infections and cancer. Transplantation is thus a therapeutic area with a large unmet medical need. Idogen's tolerogenic vaccine can provide the opportunity to improve graft survival and reduce the need for immunosuppressive drugs.

Idogen's first indication – antibodies in hemophilia A

Idogen's first tolerogenic vaccine is intended for treating patients with hemophilia A who have developed inhibiting antibodies against their ordinary treatment with factor VIII and thereby are left without efficient treatment alternatives. Hemophilia A is a rare disease, and in January 2017, Idogen received orphan drug designation for the treatment in Europe – an important value-adding step for the company as orphan drug projects has shown to have significantly higher success-rate in clinical trials. Orphan medicinal status from EMA also includes a number of

¹ Global Observatory on Donation & Transplantation in collaboration with WHO.

² Afzali B, Taylor AL, Goldsmith DJA. What we CAN do about chronic allograft nephropathy: Role of immunosuppressive modulations. *Kidney International*, 2005, 68, 2429-2443.

Wang JH, Skeans MA, Israni AK. Current status of kidney transplant outcomes: dying to survive. *Adv Chronic Kidney Dis*, 2016, 23, 5, 281-286.

PRESS RELEASE

IDOGEN AB



additional benefits, such as smaller clinical trials, support from government agencies during development and ten years of market exclusivity after launch.

For additional information about Idogen, please contact:

Lars Hedbys, CEO

Tel: +46 (0)46-275 63 30

E-mail: lars.hedbys@idogen.com

This is an English version of an original Swedish press release communicated by Idogen AB. In case of interpretation issues or possible differences between the different versions, the Swedish version shall apply. 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 the 11th of May 2017.

Idogen develops tolerogenic vaccines which re-program the immune system. The term "tolerogenic" refers to that the immune system will tolerate the selected molecule after treatment. It represents a new treatment method for autoimmune diseases, organ rejection after transplantation and patients without treatment after developing antibodies against standard treatment. The first indication for the therapy will be patients with the bleeding disorder hemophilia A who have developed an immunological reaction against their necessary factor VIII replacement. The treatment method comprises cells from the patient's blood being reprogrammed to dendritic cells with the capacity to specifically counteract the adverse immune reaction. The company's technology platform has the potential to develop long-acting treatment of anti-drug antibodies as well as autoimmune diseases that currently cannot be cured. In addition, Idogen has the potential to change the transplantation market by reducing the need for immunosuppressive therapy after transplantation. Idogen was founded in 2008 based on a fundamental immunological discovery at Lund University. For more information, visit www.idogen.com