PRESS RELEASE
IDOGEN AB

Org nr. 556756-8521
Date: 12th of December, 2016

Positive decision for Idogen's orphan designation application in Europe

The European Medicines Agency's Committee for Orphan Medicinal Products (COMP) has reached a positive decision regarding Idogen's application for orphan drug designation in Europe. This means that the COMP has made the assessment that the application meets all the necessary criteria and they will therefore recommend that the European Commission grants Idogen a formal orphan drug designation.

An orphan drug designation provides several important benefits for Idogen. A product that is classified as an orphan drug receives market exclusivity in the EU for ten years following marketing authorization, regardless of the period of validity of any patents, which is important for the value of any market position or license agreement. Idogen also receives free consultation for scientific advice, and fee reductions for regulatory applications for the marketing authorization.

"Patients with hemophilia and antibodies against the factor VIII treatment is a vulnerable patient population and there is a great need for new treatments, which COMP's decision confirms. The news is very encouraging and we are now awaiting the formal decision. Orphan drug designation is an important milestone in our development and represents a clear increase in value for this product." CEO Lars Hedbys comments.

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 12th of December 2016.

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