idogen

ENGINEERING IMMUNE TOLERANCE

Idogen is developing a first-in-class treatment platform which has the potential to fundamentally change the way we treat autoimmune diseases, transplant rejection and patient immune responses against protein based therapies.

Idogen's tolerogenic vaccines reprogram the immune system to tolerate the selected molecule which it has been reacting against. This is conceptually opposite to traditional vaccines. The treatment method is based on a small amount of the patient's own immune cells that are reprogrammed to specifically counteract an adverse immune reaction and then communicate this tolerance message to other cells of the immune system.

Idogen at a glance

Therapeutic approach

- First in class treatment mechanism with potential to create a long-term relief in areas of autoimmune disease, transplant rejection and patient-developed antibodies against biological treatments.
- Treatment methods that selectively target a defined antigen leaving the rest of the immune system fully active.
- Use of autologous (patient's own) cell therapy in the form of dendritic cells to reduce development time, cost and risk compared to traditional pharmaceutical development.
- Idogen has shown in vivo proof of concept of the cell therapy in a rat model of hemophilia A.
- Idogen's first indication is treating haemophilia A patients who have developed neutralizing antibodies against Factor VIII they receive, making the treatment functional again. A first phase I/II study is estimated to start in 2018.

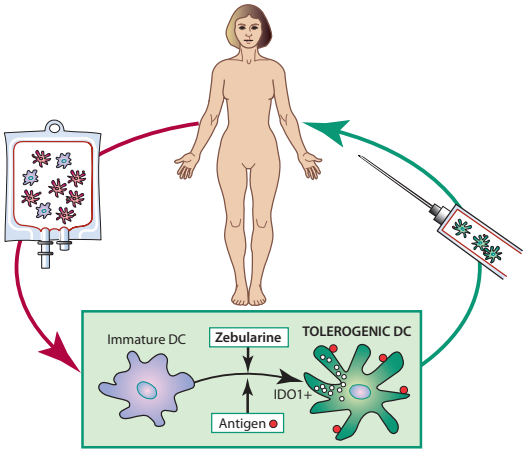
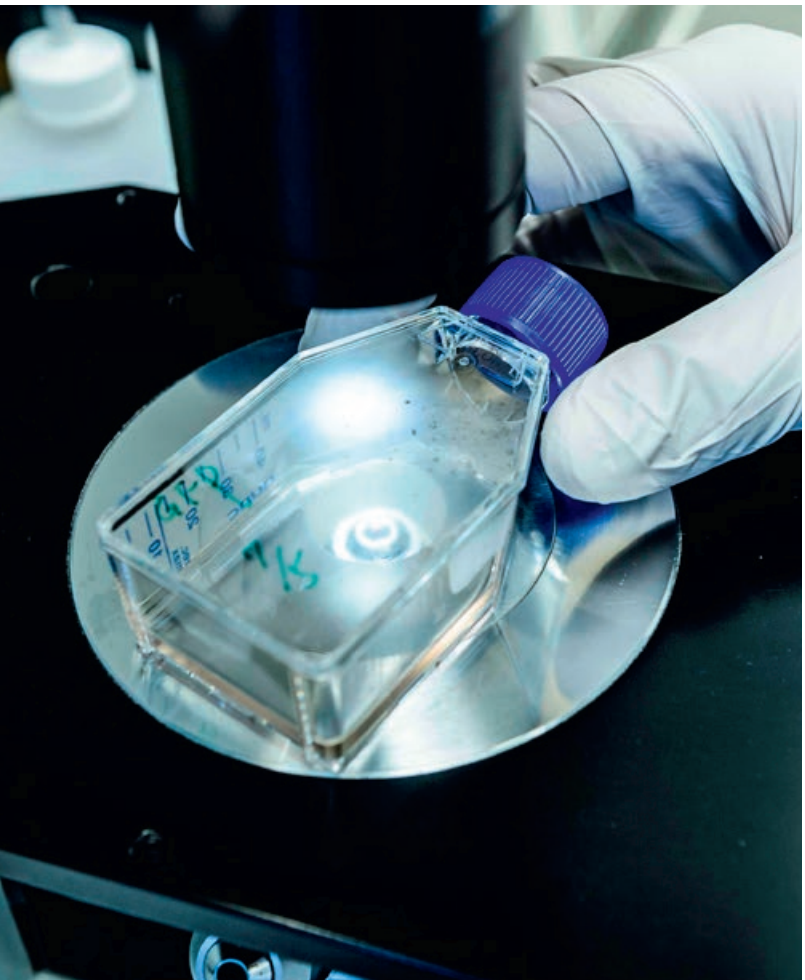


Figure 1: Idogen's treatment method involves the reprogramming of cells from patient blood to produce dendritic cells with the capacity to specifically counteract an adverse immune reaction.

Intellectual property

- Idogen has several patent families, among them a series of granted patents for treatment of autoimmune disease and prevention of transplant rejection with zebularine and derivatives, valid until 2028. Further patent applications covering other developments are pending.



People

- International team with strong experience in science, pharmaceutical development and commercialization.

Scientific rationale

- The dendritic cell is a key player in the immune system, deciding if cells or molecules should be attacked (foreign) or not (our own), see Figure 2.

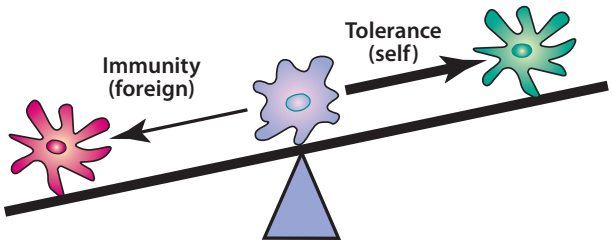
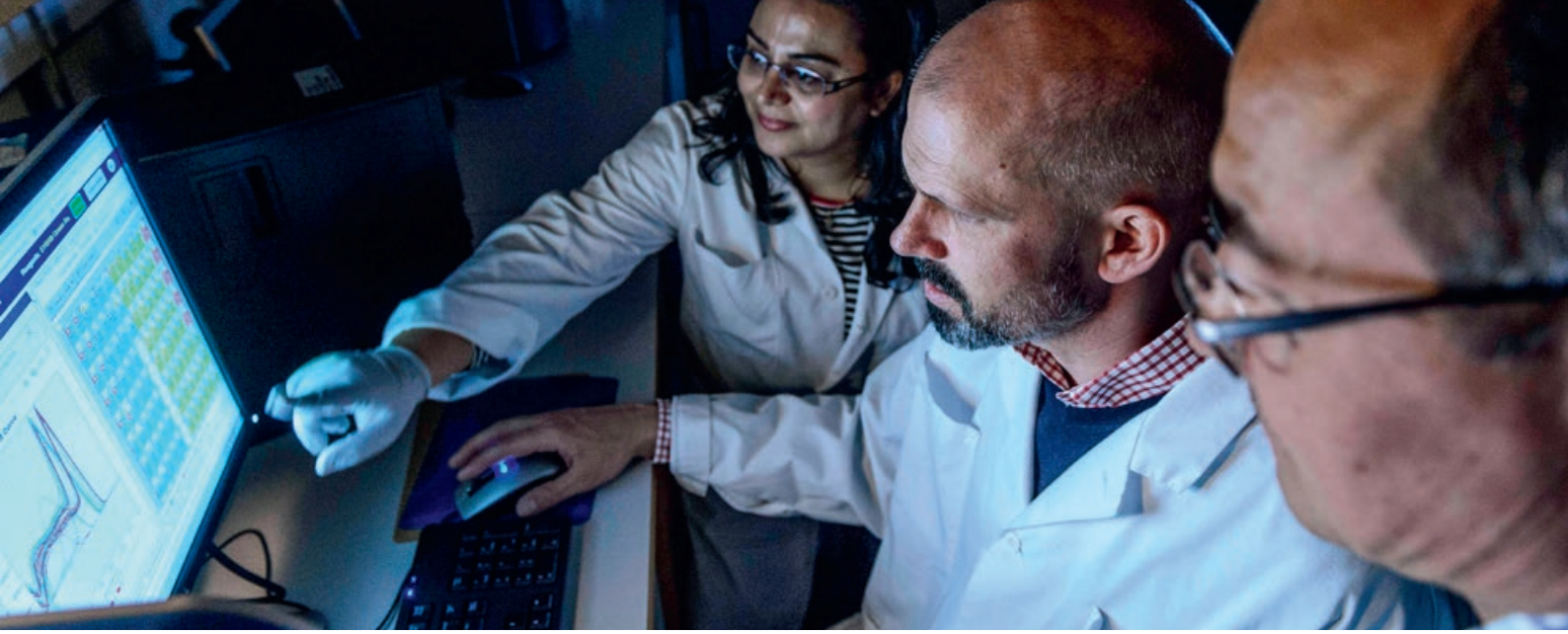


Figure 2: Dendritic cells are key players in the immune system, deciding if cells or molecules should be considered foreign and be attacked, or be considered our own and be protected. Tolerogenic dendritic cells are key cells in driving immune tolerance.

- IDO1 is an enzyme expressed by tolerogenic dendritic cells directing the development of immune tolerance. Idogen has identified a novel mechanism whereby IDO1 becomes upregulated in a therapeutically useful way.
- The process of creating a tolerogenic dendritic cell leads to a specific and long-lasting loop where the tolerance is maintained over time via the T-cells of the immune system.



Proof of concept

- The spectacular results from a study where allogeneic pancreatic islets were transplanted to diabetic rats can be seen in Figure 3 (right). Rejection was prevented by zebularine treatment ($p<0.001$, two-sided Mann Whitney test) as compared to an expected 100% rejection in the controls.
- The proof of principle has also been confirmed in a mouse model of rheumatoid arthritis, where a sustained therapeutic effect was seen over 10 days following four day's zebularine treatment.
- In a rat model of hemophilia A, treatment with Idogen's cell therapy showed a long-term effect and a significantly reduced occurrence of inhibitory antibodies.

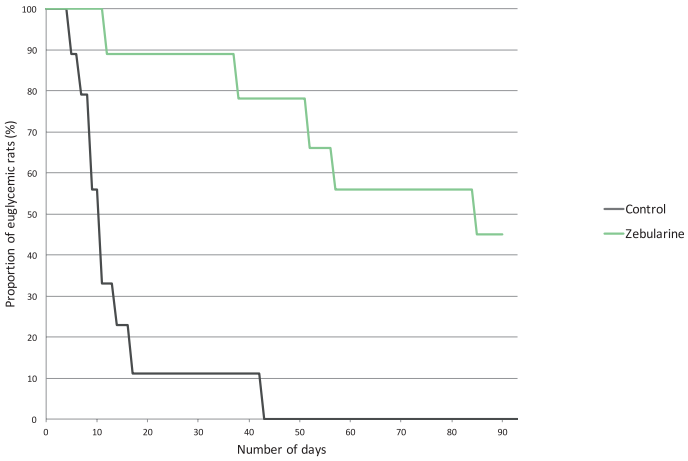


Figure 3: Proof-of-principle showing that rats which have been treated with zebularine i.p. from day 6 to day 20 had a lower degree of transplant rejection as compared to untreated controls. The study also shows that zebularine induces a sustained effect, in many cases for the whole observation period of 90 days.

Development plan

Idogen is developing a platform technology for a long-acting treatment of autoimmune diseases, prevention of transplant rejection and for reducing levels of antibodies against biological treatments. Idogen's first product is intended to treat patients with severe hemophilia A affected by neutralizing antibodies against their vital coagulation factor VIII-treatment. Hemophilia A will be the first indication for three main reasons:

- Large medical need
- Orphan designation – less extensive clinical trials, support from authorities and extended market exclusivity
- Well-defined antigen – good chance of success in developing a successful treatment

The project is in the preclinical phase and current key activities include GMP development and studies on safety and quality control. The project is expected to enter the clinical phase I/II in 2018. When the hemophilia A treatment has been validated, the concept will be extended to indications with large patient populations, such as rheumatoid arthritis and multiple sclerosis. License agreements for parts of the company's product portfolio could become an important component of the strategy.

Market potential

The segment of hemophiliacs which Idogen plans to treat is expected to generate a revenue of over 200 million USD annually in Europe and USA. There are over 100 autoimmune diseases, where rheumatoid arthritis, type-I-diabetes and multiple sclerosis (MS) are the more prevalent ones. The market potential for rheumatoid arthritis is estimated to be in the order of 2 billion USD annually just in Europe and the USA at a market penetration of 10% of new cases or 1% of present patients. The price level is calculated in line with existing cell therapy, which is approximately 50 000 USD per patient. After the vaccination treatment the company's ambition is that treatment effect should be long-lasting, in line with other vaccinations.

The Idogen team

Management team

Lars Hedbys

PhD, Chief Executive Officer

20 years of executive positions in life science in pharma and medtech and Vice President and Site General Manager roles in AstraZeneca, Co-founder of Idogen AB, Regenesance BV, IAmPatient AB and Casigen Pharma Ltd.

Ingvar Karlsson

Chief Financial Officer

Broad experience from CFO and controller-positions in large, listed companies.

Anette Sundstedt

PhD, Chief Scientific Officer

Over 15 years of experience in research and development in the pharmaceutical industry. Anette has previously led a research group focusing on immunological tolerance at Lund University and conducted research in immunotherapy for autoimmune diseases at the University of Bristol, UK.

Dennis Henriksen

PhD, Chief Technical Officer

Over 20 years of managerial industry experience and of developing and implementing cGMP in small to medium size biotechnology companies.

Neil Thomas

PhD, Chief Business Officer

Over 18 years of experience from life science in company formation, fund-raising, IP portfolio management, business development and licensing.

Idogen's Listing

Idogen is listed on AktieTorget, a multilateral trading facility in Stockholm, Sweden.

Stock Name ..... Idogen
Ticker Name ..... IDOGEN
ISIN Number SE0006887386
OrderBookID 110089
Number of shares 9 790 045
First Traded ..... June 12th 2015
Market Cap ..... 6.93 M USD (June 9th 2016)

Photo: Kenneth Ruona, **illustration:** Lena Lyons

Major shareholders (per March 31st 2016)

Owner	Capital and votes %
HCN Group AB	10.03
Ventac Holding (Cyprus) LTD (founder)	9.27
Olov Sjögren (founder)	6.95
Leif-Göran Salford (founder)	6.76

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