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novio sense
glucose sensor

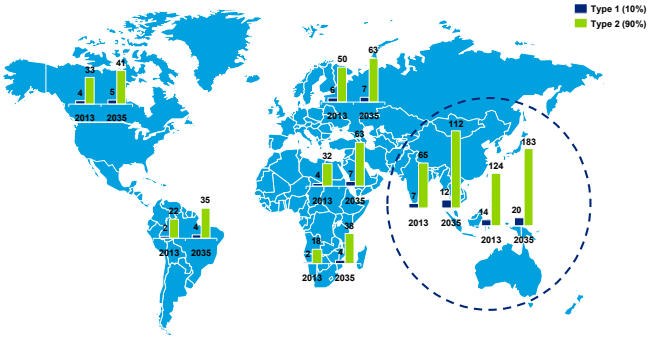
NovioSense
Tear Glucose Sensor

NovioSense will improve the glucose management of diabetes patients by removing the painful fingerprick and thus to significantly improve the quality of life of people living with diabetes

‘Global population suffering from diabetes will almost double in coming 20 years’

Diabetes populations is growing

Diabetes is a huge and significantly growing problem. In 2013 globally 382m people suffered. At the current growth rate this number is estimated to rise to 592m in 2035 by the international diabetes populations.



Source: population suffering from Diabetes idf.org, assumption made of the split type 1/2 based on global data (10% vs 90%)

Managing glucose levels for diabetics is done via monitoring devices

Glucose monitoring technology has been used in the management of diabetes for three decades. Many technologies are being pursued to develop novel glucose sensors, including non-invasive continuous monitors. However, none of the devices in production at present meet the criteria for the ideal sensor and can replace the painfull fingerprick. As diabetes continuous to become ever more prevalent, the need for improved technology is clear.

At the moment, there is no solution available on the market to monitor glucose levels in real-time and wireless and non-invasive manner

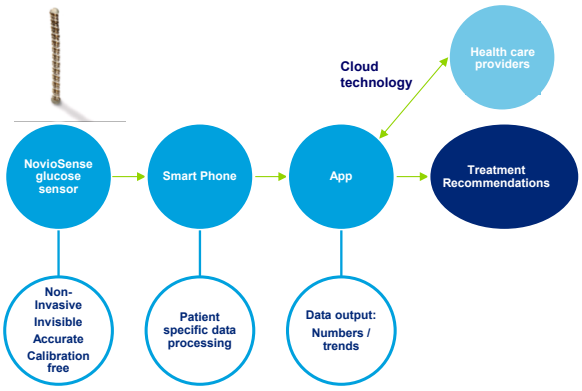
For millions of people with diabetes, controlling blood sugar levels is vital to manage their condition and prevent complications. But pricking your finger to test blood glucose is painful and can be distressing. It is also one of the reasons that many people with diabetes don’t test as much as they need to, which can put their health at risk.

NovioSense developed a non invasive tear glucose sensor

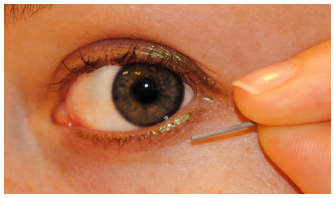
Challenged with this knowledge and by the fact that there is no solution available to address the urgent needs identified by patients and endocrinologists, NovioSense has developed a new type of glucose sensor.

This cutting-edge device doesn’t use blood to measure blood glucose. It is a non-invasive, wireless sensor to monitor glucose levels in tear fluid to enhance care and treatment of diabetes patients.

The glucose-measuring device consists of a 15 mm-long, metal coil that is coated in a hydrophilic gel, and which the patient drops into the bottom eyelid. The coil moves to the correct place in the eye and the gel coating hydrates and swells, creating a contact between the metal coil and the fluid in the eye.



NovioSense has developed a platform technique to measure different metabolites in basal tear fluid, based on a non-invasive sensor that is not visible when worn by subjects. Tears are a rich source of biomarkers and NovioSense has developed a miniature electrochemical sensor that is capable of detecting these biomarkers and their respective concentrations, via an enzymatic reaction using an electrochemical cell.

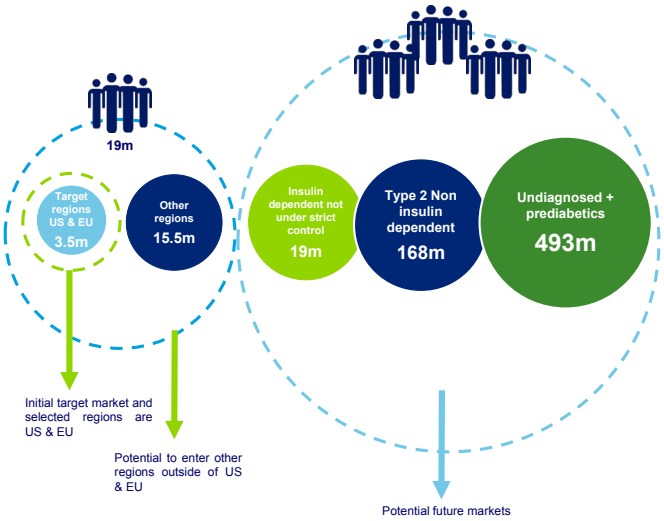


The NovioSense sensor is placed in a pocket of skin on the lower part of the eye called the conjunctivial fornix, otherwise know as the

lower eyelid. This pocket is filled with tear fluid and provides an ideal location for measurement of metabolites in basal tear fluid, ensuring that the sensor is continuously surrounded by tear fluid in the basal tear fluid flow of the eye.

It is the vision of NovioSense to enable patients to take back control of their life by measuring biomarkers in a non-invasive and unobtrusive manner. The first goal is to accomplish this for diabetic patients by providing a pain free alternative to finger prick and continuous monitoring solutions.

There are 38 million diabetics who are insulin dependent and require a finger prick on a regular basis. The initial target market for NovioSense is the group of patients that are insulin dependent and



on strict control in the US and the EU, because this market is most easy to access and has the most urgent unmet need. Total estimated number of patients within this group in the US and EU is approximately 3.5m. However, after a couple of years after market launch, NovioSense will become more of a replacement of the finger prick opening up the market of insulin dependents who are not on a strict control (19m patients, US + EU 7.4 million). Furthermore, the NovioSense glucose sensor can also be of benefit for non insulin dependent diagnosed patients (168m patients). For this group the focus is to give them alarms and enhance their self management to empower and improve lifestyle for patients. From the group of non insulin dependent diagnosed Type 2 patients the focus would be first on the group which are borderline to be insulin dependent. Finally, pre diabetics (obese) and undiagnosed people (493m) can highly benefit from the sensor.

Regulatory pathway

NovioSense is currently finalizing their glucose sensor and the first animal study has been conducted successfully, providing proof of concept and showing that tear glucose levels can be measured accurately with a good signal-to-noise ratio.

The sensor can be classified as a class IIb medical device in the route to CE marking. NovioSense will first apply for CE certification in Europe and with the support of the EU Technical File for obtaining the CE mark, the FDA submission file will be compiled.

IP protection via patent family

NovioSense is building a patent family portfolio to protect its product. The first patent family was filed in 2012 and has a priority date of 18 April 2011.

Two international patent (PCT) request have been filed with respect to the NovioSense continuous glucose sensor. The patent applications have been converted in a number of applications in specific countries.

Contact

NovioSense is seeking addiotional venture capital participation. For further information on NovioSense and its products, please contact:

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