



NovioSense Tear Glucose Sensor Phase 2 Clinical Data Update

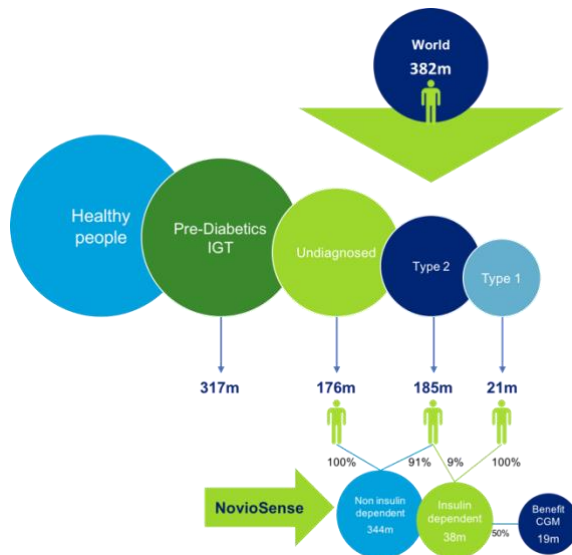


NovioSense has conducted successful phase 2 clinical trials of its glucose management platform

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

Diabetes populations are growing

In 2013, globally 382m people suffered from diabetes. At the current growth rate, this number is estimated to rise to 592m in 2035 by the international diabetes federation.



Source: population suffering from Diabetes idf.org, assumption made of the split type 1/2 based on global data (100% vs. 90%)

Now, there is no solution available on the market to monitor glucose levels in a real-time, 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 also plays a role in contributing to the number of patients who intentionally avoid taking the test as often as they should, which can prove to be a significant risk to their health.



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 determine glucose values. It is a wireless sensor enable monitoring glucose levels in tear fluid to enhance care and treatment of diabetes patients. The miniaturized sensor device links to any NFC enabled cell phone and can compete at a much lower price point than existing technologies.

The glucose-measuring device consists of a small coil coated in a hydrophilic gel. The sensor can be easily placed by patient into the bottom of the eyelid in which the gel coating hydrates and swells, creating a contact between the coil and the fluid in the eye. The device is not visible and can be worn comfortably in the lower eye lid.



Additionally, NovioSense has developed a universal sensor technology to measure different metabolites in basal tear fluid. Tears are a rich source of biomarkers and the NovioSense miniature electrochemical sensor can detect these biomarkers and their respective concentrations.

The non-invasive nature of NovioSense will disrupt the market by allowing all diabetic patients to measure their glucose on demand.

There are 38 million diabetics who are insulin dependent and require a finger prick on a regular basis. The non-invasive nature of the NovioSense device is attractive not only for those who want to eliminate the finger prick (Type 1) but also for those who do not currently finger prick but may benefit from enhanced control of glucose (Type 2). The total estimated number of patients within the NovioSense target group in the US and EU is approximately 200m. For the latter group, the focus is to give them alarms and improve their self-management. Additionally, to empower and improve lifestyle for patients. Finally, pre-diabetics (obese) and undiagnosed people (493m) can highly benefit from the sensor as part of a preventative regime.

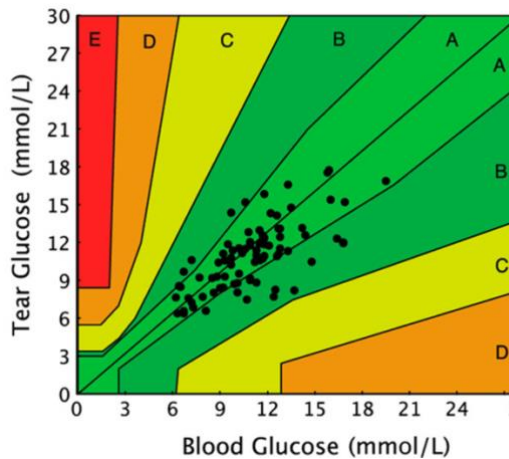


The core of the NovioSense technology is the combination of miniaturized electronics and chemical know-how.

As a spin out of the Fraunhofer Society and comprised and with a strong R&D team specializing in chemistry and chemical engineering NovioSense is uniquely positioned to develop their biosensor platform. Miniaturized application specific integrated circuits developed together with Fraunhofer have been combined with NovioSense's in house coating technologies to produce sensor devices that are highly sensitive, tolerant to interference while retaining the level accuracy rivaling invasive type of sensing devices.

Status of developments

NovioSense was founded in 2012 and has continually developed and refined their sensor and coating technology in response to pre-clinical trials as well as competitor testing and benchmarking. With successful clinical safety trials completed, NovioSense completed the first round of second phase of clinical trials in 2018, providing proof of concept and showing that tear glucose levels can be measured accurately with a good signal-to-noise ratio. Initial correlation data from Type 1 diabetic patients shows that blood glucose and tear glucose follow each other in a rather close correlation. Further trials are planned to expand the existing data set to a total of 30 patients.



Initial consensus error grid data shows that the device meets acceptable accuracy criteria for market introduction.

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.

Three international patent (PCT) requests have been filed concerning the NovioSense continuous glucose sensor. The patent applications have been converted in several applications in specific countries. The first two patent applications have been granted in EU, Japan and China and it is expected that US coverage will be issued in 2017.

Contact

NovioSense is seeking additional financing for its series A activities as well as out licensing or co-development opportunities for its antifouling coating technology. For further information on NovioSense and its products, please contact:

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