personalised Diabetes Management using lOw-cost Needle-free multiple-biomarkers monitoring Device

Reporting

Project Information

DiaMOND

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Project website

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Project closed

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Coordinated by
INDIGO DIABETES
Belgium

Periodic Reporting for period 3 - DiaMOND (personalised Diabetes Management using lOw-cost Needle-free multiple-biomarkers monitoring Device)

Reporting period: 2021-01-01 to 2021-06-30

Summary of the context and overall objectives of the project

Diabetes is the #1 health challenge of the 21st century. Continuous Glucose Monitoring or CGM ($1.25B market in 2016, growing 29%/yr) is today's cornerstone of "diabetes self-management" and the most effective solution to reduce the economic and societal burden of diabetes. But the shortcomings of current CGMs hinder their wider adoption: high cost, unsatisfactory predictability of severe events, and poor user comfort. The DiaMOND project removes these barriers by bringing a longterm, implantable, cost-effective Continuous Diabetes Monitoring (CDM®) to the market. The CDM sensor will, as a first, allow personalised management by accurately monitoring all the biomarkers at play in diabetes control, and not only glucose. CDM can prevent severe clinical events such as hypo- and hyperglycaemia and ketoacidosis, rather than just monitoring them. Indigo's CDM uses Indigo's patented multi-biomarker spectrometer integrated on a chip that is implanted subcutaneously.
With DiaMOND Indigo has proven that it can measure glucose, ketones and lactate accurately, continuously and in RT in vivo in an animal model with its invisible, subcutaneously inserted sensor. Lactate has been identified as a potential marker for increased insulin need. A small-scale investigational clinical study is on its way to reproduce this demonstration. The market access strategy has been investigated including KOL involvement and dissemination to the broad public and diabetes community.
DiaMOND was of uttermost importance and detrimental to bring Indigo to the stage it is now, and the results will realm in the near future and strengthen Indigo's path towards valorisation. This world's first holds the promise to address the need of millions of people living with diabetes.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

During the third and final phase of the project (January 2021-June 2021) we have geared all resources towards:
-Demonstration of the world's first fully implanted, invisible multimetabolite sensor with impressive prediction accuracies in-vivo in humans in our First-in -Human Study GLOW.

Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)

Continuous Glucose Monitoring (CGM) is today's cornerstone of "diabetes self-management" and has proven itself as the most effective solution to reduce the economic and societal burden of diabetes. Current CGM devices suffer, however, from drawbacks that hinder their wider adoption: reliability and predictability of severe events are low, user comfort and discreteness are poor and cost is high. On top of this, new successful treatments such as SGLT-2 inhibitors introduce new risks such as Diabetes Keto-acedosis (DKA) that requires companion diagnostics.
The DiaMOND project aimed at removing these barriers by bringing a disruptive Continuous Diabetes Monitoring (CDM) system to market. This CDM medical device will for the first time allow personalised diabetes management by accurately monitoring all the relevant biomarkers and not only glucose.

Diabetes is essentially a disease of the body's energy delivery and storage system and is controlled by both the glucose and the lipid metabolism. Measuring only glucose cannot result in reliable and consistent diabetes management. For the very first time, diabetes patients will have with Indigo's CDM the tools to prevent severe, critical events, and not only monitor them.
With the DiaMOND project, we have proven for the very first time world wide the successful operation of a fully implantable, invisible multibiomarker at clinical accuracies in-vivo (animal model – VIPP study and human model – GLOW study). Lactate has been identified as a potential marker for increased insulin need (Action 1 – investigational clinical study).

img-action-1.jpg

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