



FOR IMMEDIATE RELEASE

Indigo Diabetes Initiates First Clinical Study of its Continuous Glucose Monitoring Sensor

Ground-breaking subcutaneous sensor aims to continuously monitor multiple metabolites including ketones in people living with diabetes

BELGIUM - Ghent, March 18, 2021 – Indigo Diabetes N.V. ('Indigo' or the 'Company'), a pioneering developer of medical solutions using nanophotonics, announces that its continuous multi-metabolite ('CMM') sensor has been successfully implanted subcutaneously in the first three participants of its first clinical study, designed to evaluate the device. Indigo's CMM sensor is in development for the continuous measurement of glucose, ketone and lactate levels in people living with diabetes.

Indigo is developing its CMM sensor as part of a next generation of Continuous Glucose Monitoring ('CGM') systems, designed to give people living with diabetes access to information on their glucose and other metabolite levels at any given time, without requiring them to wear an external device on their body.

The GLOW study (listed on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04782934) under the identifier [NCT04782934](https://clinicaltrials.gov/ct2/show/study/NCT04782934)), will be conducted at the Antwerp University Hospital, Belgium, and will enroll seven participants. It is a prospective, single-center early feasibility study designed to evaluate the safety of the sensor and the short-term integration into the tissue.

Professor Christophe De Block, Principal Investigator of the Study at Antwerp University Hospital added: *"It is essential that people with diabetes are able to accurately monitor their metabolite levels to prevent fluctuations that can seriously affect their health. At the moment ketones cannot be monitored, which means that people living with diabetes are unaware of the levels of this important metabolite, making them potentially vulnerable to ketoacidosis. The GLOW study will help us take a first step towards providing a potentially transformative new solution for these patients."*

Dr Danaë Delbeke, CEO, Inventor and Co-founder of Indigo Diabetes N.V. commented: *"Initiating our first clinical trial is a momentous event for everyone at Indigo Diabetes, and we are thrilled to be passing this significant milestone as a business. Our CMM sensor technology could revolutionise the experience of patients with diabetes reliant on constant and exhausting monitoring regimes to stay healthy. We look forward to updating the diabetes community on our progress in due course."*

Further details on the GLOW Study

The GLOW study will recruit three healthy subjects, and four subjects with type 1 diabetes. Participants receiving the CMM sensor will have the sensor inserted up to 10 mm deep in the subcutaneous abdominal tissue using local anaesthetic. The sensor will remain *in situ* for 30 days after which it will be removed. Each participant has 6 measurement visits planned over the 30-day insertion



period, during which data for glucose, lactate and ketone levels is collected and compared to applicable standards under controlled circumstances (hypo/hyperglycemia, anaerobic exercise, ketogenic conditions and during administration of potential interferents such as NSAIDS, vitamin C).

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About Indigo Diabetes N.V.

Indigo Diabetes N.V. (Indigo) is a pioneering developer of medical solutions utilizing nanophotonics. Indigo was founded by Danaë Delbeke and her team in 2016. Today Indigo is developing the world's first invisible sensor for people living with diabetes to address their need for continuous accurate glucose and ketone monitoring with an improved user experience. Indigo exploits groundbreaking photonics technology responsible for revolutionizing the Internet to transform diabetes management. Indigo is based in Ghent, Belgium. Find out more at www.indigomed.com.

About Indigo Diabetes's CMM sensor

Indigo Diabetes's CMM sensor is a small spectrometer-on a-chip to monitor *in-vivo* simultaneously and continuously multiple metabolites. The inert, miniature integrated silicon photonics spectrometer chip measures the absorption of light in the interstitial fluid to quantify the concentration of multiple metabolites simultaneously without the use of enzymes or fluorophores. Once inserted under the skin the CMM sensor is invisible to the naked eye and will connect securely and wirelessly to mobile devices to show and capture the concentration profiles of the metabolites for the user. A rechargeable sensor battery powers the measurements. It is expected that the sensor will have a lifetime up to 2 years. Preclinical studies have successfully demonstrated proof of concept with promising accuracy.

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