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KNOW LABS

Know Labs' Non-Invasive Glucose Monitor Achieves 11.1% MARD in Latest Clinical Research Study

Know Labs' first study including participants with diabetes and venous blood as a comparative reference demonstrates its proprietary sensor's accuracy and medical application.

SEATTLE--(BUSINESS WIRE)-- Know Labs, Inc. (NYSE American: KNW), an emerging developer of non-invasive medical diagnostic technology, today announced interim results from its most recent clinical research study. The study assessed the accuracy of Know Labs' proprietary radiofrequency (RF) dielectric sensor in non-invasively measuring blood glucose in participants with prediabetes and Type 2 diabetes using venous blood as a comparative reference – resulting in an overall Mean Absolute Relative Difference (MARD) of 11.1%.

Dr. Virend K. Somers of the Mayo Clinic serves as an author and co-investigator on the clinical research protocol. Dr. Somers will present the interim results of the study titled, "Non-Invasive Blood Glucose Monitoring in People with Diabetes Using an RF Sensor and Venous Blood Comparator" at the 17th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD) in Florence, Italy on March 6-9, 2024.

"Achieving this level of accuracy in the first study using a blood reference device is truly remarkable," said Larry Ellingson, former Chair of the Board of the American Diabetes Association, Founding Member of the Diabetes Leadership Board and current member of Know Labs' Board of Directors. "Despite significant efforts in the development of non-invasive blood glucose monitoring solutions, delivering a highly accurate, economical, FDA-cleared non-invasive continuous glucose monitor (CGM) still remains to be seen. These results from ongoing clinical research reflect the impressive and continued stability of Know Labs' novel sensor technology and algorithms, bringing the company one step closer to delivering its FDA-cleared non-invasive CGM to the masses."

Study Design

This is Know Labs' first clinical research protocol involving people with diabetes and using venous blood as comparative reference. The proprietary RF sensor employed in the study measures glucose levels using dielectric spectroscopy by rapidly scanning a large range of RF frequencies and recording voltage values detected at each frequency to quantify, with trade-secret machine learning (ML) algorithms, real-time continuous blood glucose levels. The sensor continuously scanned participants' forearms during 21, three-hour sessions involving a 75g Oral Glucose Tolerance Test. Venous blood samples were collected using a peripheral intravenous catheter every five minutes and analyzed using an FDA-cleared blood glucose hospital meter as a reference device.

Data was prepossessed using smoothing techniques and an 80/20 split was performed to

create model training and test datasets, respectively. Know Labs trained a Light Gradient Boosting Machine model on data consisting of 520 paired RF and reference blood glucose values, then tested on 130 held-out paired values.

Results

On the held-out test dataset, blood glucose was estimated with a MARD of 11.1 ± 2.1% relative to venous blood. Similar accuracy was observed in normoglycemic (11.0 ± 2.7%) and hyperglycemic (11.5 ± 3.1%) ranges.

In previously published studies, most of the data collected was within the normoglycemic range (70 to 180 mg/dL) and glucose values from a popular CGM were used as comparative reference. By including participants with Type 2 diabetes, this study significantly increased the number of data points outside the normoglycemic range, specifically within the hyperglycemic range (>180 mg/dL). Demonstrating similar accuracy across both ranges is an important milestone in Know Labs' technology development roadmap. While many devices typically underperform outside the normoglycemic range, these results suggest that the novel RF sensor, paired with trade-secret ML algorithms, holds considerable promise for the non-invasive measurement of blood glucose.

Last week, Know Labs announced the KnowU™, its wearable, non-invasive CGM that incorporates the sensor the Company plans to submit to the FDA for clearance. Know Labs will exhibit the KnowU device at the ATTD Tech Fair (Booth #30) throughout the conference and during a dedicated session presentation on Thursday, March 7 from 4:30-4:40 p.m. CET. Know Labs will also sponsor an invitation-only luncheon hosted by Children With Diabetes (CWD), where prominent thought leaders in the diabetes management field will discuss the latest in non-invasive glucose monitoring innovation.

These early results are part of a larger, now completed clinical trial with up to 100 participants focused on a population with diabetes and prediabetes, conducted September 2023 through February 2024. During 2024, Know Labs will also deploy the KnowU in large-scale, external clinical trials while making refinements to the device and its algorithms. These new studies will help determine the technology's performance throughout continuous wear, in more real-world environments, and within more expansive glycemic ranges, including the hypoglycemic range (<70 mg/dL). To stay updated on the latest results, visit www.knowlabs.co/research-and-development.

About Know Labs, Inc.

Know Labs, Inc. is a public company whose shares trade on the NYSE American Exchange under the stock symbol "KNW." The Company's platform technology uses spectroscopy to direct electromagnetic energy through a substance or material to capture a unique molecular signature. The technology can be integrated into a variety of wearable, mobile or bench-top form factors. This patented and patent-pending technology makes it possible to effectively identify and monitor analytes that could only previously be performed by invasive and/or expensive and time-consuming lab-based tests. The first application of the technology will be in a product marketed as a non-invasive glucose monitor. The device will provide the user with accessible and affordable real-time information on blood glucose levels. This product will require U.S. Food and Drug Administration clearance prior to its introduction to the market.

Safe Harbor Statement

This release contains statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements appear in a number of places in this release and include all statements that are not statements of historical fact regarding the intent, belief or current expectations of Know Labs, Inc., its directors or its officers with respect to, among other things: (i) financing plans; (ii) trends affecting its financial condition or results of operations; (iii) growth strategy and operating strategy; and (iv) performance of products. You can identify these statements by the use of the words “may,” “will,” “could,” “should,” “would,” “plans,” “expects,” “anticipates,” “continue,” “estimate,” “project,” “intend,” “likely,” “forecast,” “probable,” “potential,” and similar expressions and variations thereof are intended to identify forward-looking statements. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond Know Labs, Inc.’s ability to control, and actual results may differ materially from those projected in the forward-looking statements as a result of various factors. These risks and uncertainties also include such additional risk factors as are discussed in the Company’s filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended September 30, 2023, Forms 10-Q and 8-K, and in other filings we make with the Securities and Exchange Commission from time to time. These documents are available on the SEC Filings section of the Investor Relations section of our website at www.knowlabs.co. The Company cautions readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. The Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made.

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