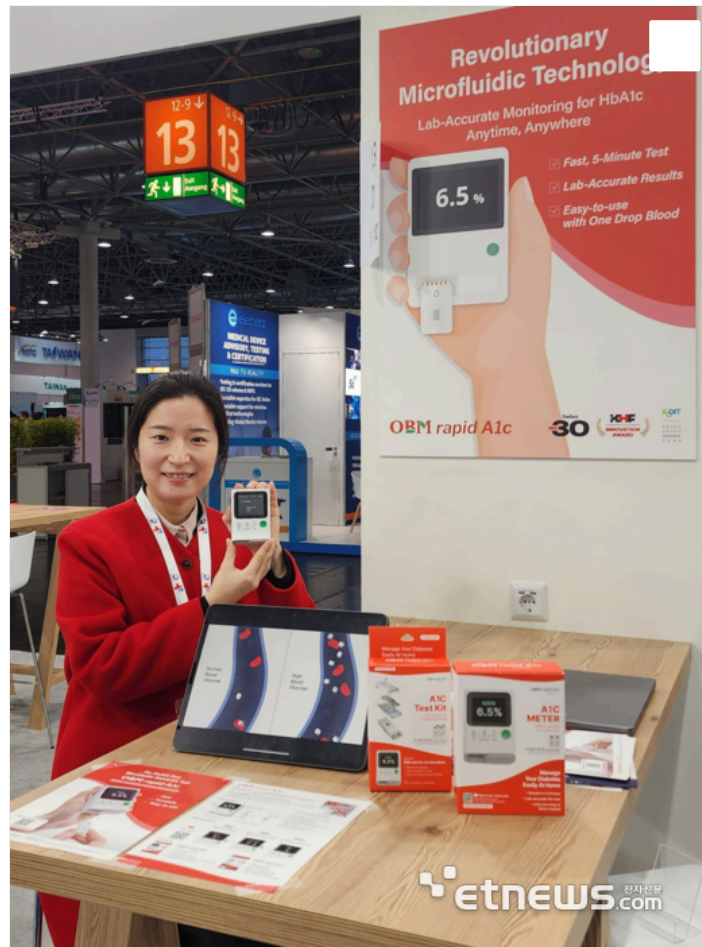


Orange Biomed “Measuring Glycated Hemoglobin at Home... Overseas Challenge”

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Park Ye-seul, CEO of Orange Biomed

Bio startup Orange Biomed is entering the global market with its personal glycated hemoglobin (HbA1c) measuring medical device. Based on its miniaturization technology, it is targeting diabetic households and seeking US Food and Drug Administration (FDA) certification to pioneer the market.

Park Ye-seul, CEO of Orange Biomed, said, “We have conducted clinical trials with a US clinical trial contract organization (CRO) and are conducting non-clinical tests to obtain approval, which will be completed in the first half of next year,” and added, “We plan to apply for FDA approval in the second half of the year.” She continued, “We expect to sell the product as early as 2026.”

A person with a glycated hemoglobin level of 6.5% or higher is classified as diabetic. When blood sugar levels rise, numerous red blood

cells in the blood become glycosylated, which is called glycosylated hemoglobin. Red blood cells are soft and bend to pass through capillaries, but when glycosylated, they become hard and cannot pass through. This can cause various complications.

To measure glycosylated hemoglobin, which is a protein, a protein quantification method is used. This method cannot be used in cell units and has several limitations, such as the need for refrigerated storage of protein reagents, so it can only be used in medical institutions.

Orange Biomed's innovation lies in the method of measuring glycosylated hemoglobin using microfluidic technology. Instead of a protein quantitative method, a physical method that measures the hardness of red blood cells was adopted.

CEO Park said, "Microfluidic technology can analyze red blood cells at the single cell level and precisely measure glycosylated hemoglobin levels." He added, "We applied the principle of measuring red blood cells passing through microfluidic tubes that simulate capillaries with a drop of blood."



Portable glycosylated hemoglobin meter 'OBM rapid A1c'

The company created the 'OBM rapid A1c', a miniaturized portable measuring device using this technology. When blood is dropped into a USB-type disposable cartridge, the glycosylated hemoglobin level is displayed on the display. It is convenient because it does not require refrigeration.

Orange Biomed aims to obtain FDA approval in the second half of the next year. In addition to advancing into the US, it also plans to advance into regions with low medical accessibility, such as the Middle East, Africa, and South America. At the global medical device fair MEDICA held in Germany last November, it confirmed high interest from buyers in the Middle East and Africa. The company plans to actively target demand in medically underserved areas and expand international partnerships and cooperation in the future.

CEO Park said, "It is difficult to measure glycated hemoglobin in regions where medical infrastructure is lacking and refrigeration and electricity supply are difficult, but our technology is suitable for these markets because it has few environmental restrictions." He added, "You can now check glycated hemoglobin at home, which used to be possible only at hospitals."

Orange Biomed, which recently succeeded in attracting Series A1 investment, plans to focus on clinical trials. It is also preparing to develop other medical devices using its core technology, microfluidic technology.

Park said, "We are currently at a point where we need to scale up our team, so we plan to hire a variety of talents, including a strategy manager, a sales director, PhD-level R&D personnel, and licensing experts," adding, "We want to work with talented individuals to grow together as a company that helps diabetes patients."

Reporter Song Hye-young hybrid@etnews.com



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