Medtronic News

Medtronic announces FDA approval of Simplera™ CGM and global partnership with Abbott

Medtronic Diabetes expands CGM offerings to meet more people where they are in their diabetes journey

DUBLIN, Aug. 7, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced the U.S. Food and Drug Administration (FDA) approval for its Simplera™ continuous glucose monitor (CGM) — the company's first disposable, all-in-one CGM that's half the size of previous Medtronic CGMs. The discreet design simplifies the insertion and wear experience, eliminating the need for overtape.

The Simplera™ platform featuring the company's newest CGM form factor, includes the Simplera™ CGM, designed to be used as part of a Smart MDI system with the InPen™ smart insulin pen and the Simplera Sync™ sensor, which is designed to be integrated with the MiniMed™ 780G system.

The Simplera™ CGM and Simplera Sync™ sensor are CE Marked inEurope and launched earlier this year with positive feedback around ease of use and insertion, adding to the existing high satisfaction with the MiniMed™ 780G system.

The recent FDA approval for Simplera™ CGM lays the groundwork for future submission of the updated InPen™ smart insulin pen app, which would facilitate integration with Simplera™ CGM, as a Smart MDI system. Once FDA clearance is obtained, Medtronic will initiate a limited market release in the U.S. beginning with existing standalone CGM and InPen™ customers. The Simplera Sync™ sensor is under review by the FDA in a separate regulatory filing. It is investigational in the U.S. and not approved for commercial use.

Additional global regulatory submissions and approvals of the Simplera™ CGM and Simplera Sync™ sensor are pending.

Global Partnership to Complement Future Medtronic CGM Offerings

Medtronic is excited to announce a global partnership with Abbott to expand CGM options for people living with diabetes. Under this unique agreement, the companies will collaborate on an integrated CGM based on Abbott's most advanced CGM platform. Abbott will supply Medtronic with a CGM that will work exclusively with Medtronic smart dosing devices and software across both automated insulin delivery and Smart MDI systems. These systems, including the Abbott-based CGM, will be sold exclusively by Medtronic. Medtronic expects this original equipment manufacturer (OEM) agreement to be accretive to Diabetes revenue and neutral to Diabetes gross margin. Additional financial terms of the partnership and timing for commercial availability were not disclosed.

"Our partnership with Abbott allows us to expand access to our advanced automated insulin delivery and Smart MDI systems that deliver best-in-class outcomes with the most widely used CGM in the world. We look forward to offering our Simplera™ platform alongside this integrated CGM to bring more choice to people living with diabetes within one seamless Medtronic experience," said Que Dallara, executive vice president and president, Medtronic Diabetes.

Medtronic continues to advance its pipeline for people requiring intensive insulin delivery, including next-generation durable and patch automated insulin delivery systems, smart pens, CGMs, algorithms, software and services and will continue to expand therapy indications.

"This partnership pairs two global leaders in glucose sensing technology and insulin delivery," saidJared Watkin, executive vice president of Abbott's diabetes care business. "Abbott's CGM technology has set the standard for accurate, accessible, easy-to-use and reliable continuous glucose monitoring. Connecting this CGM built for Medtronic's advanced insulin delivery systems and algorithms makes it easier for people to spend less time thinking about their diabetes and more time living."

About the Diabetes Business at Medtronic (www.medtronicdiabetes.com)

Medtronic Diabetes is on a mission to alleviate the burden of diabetes by empowering individuals to live life on their terms, with the most advanced diabetes technology and always-on support when and how they need it. We've pioneered first-of-its-kind innovations for over 40 years and are committed to designing the future of diabetes management through next-generation sensors (CGM), intelligent dosing systems, and the power of data science and AI while always putting the customer experience at the forefront.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on LinkedIn.

Any forward-looking statements, including, but not limited to, statements regarding the partnership between Medtronic and Abbott, strategic and other potential benefits of the partnership, Abbott's products and product candidates, and other statements about Medtronic managements' future expectations, beliefs, goals, plans or prospects, are subject to risks and uncertainties including, but not limited to, the ability to obtain regulatory approvals, and other risks and uncertainties such as those described in Medtronic's reports and other filings with the Securities and Exchange Commission. Actual results may differ materially from anticipated results. Medtronic cautions investors not to place considerable reliance on the forward-looking statements contained in this press release. These forward-looking statements speak only as of the date of this document, and Medtronic undertakes no obligation to update or revise any of these statements except to the extent required by law.

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