Medtronic Secures Two CE Mark Approvals for Guardian 4 Sensor & for InPen MDI Smart Insulin Pen

New No Fingerstick1 Sensor Integrates with Both the MiniMed 780G System and the Smart InPen System

DUBLIN, May 26, 2021/PRNewswire/ --Medtronic plc(NYSE:MDT), the global leader in medical technology, today announced CE (Conformité Européenne) Mark for expanded functionality of the company's InPen™ smart[2] insulin pen for multiple daily injections (MDI). The company also announced CE Mark for its Guardian™ 4 sensor[3], which requires no fingersticks[1] for calibration or diabetes treatment decisions. The CE Mark allows this next-generation sensor to be integrated with either the MiniMed™ 780G insulin pump system or InPen, or for stand-alone continuous glucose monitoring (CGM) use. These latest innovations will begin commercial launches in European markets later this Fall (Q2 FY22).

"We look forward to having multiple ways to help our patients manage their diabetes as we know that patient needs and preferences can vary greatly," said Prof. Goran Petrovski, M.D., MSc, Ph.D., diabetologist – Endocrinology Unit,Sidra Medicine, Doha, Qatar. "Living with diabetes is challenging, and these innovations are finding new ways to reduce the work that people must do every day to stay healthy."

The InPen is the first and only smart insulin pen approved inEurope that's integrated with real-time[4] CGM via one convenient smartphone app. The smart MDI system automatically records insulin doses, tracks active insulin, and recommends mealtime and correction doses based on an auto-populated bolus calculator. By combining InPen with the Guardian 4 CGM system, it will provide real-time glucose readings and alerts alongside insulin dose information giving users everything they need to manage their diabetes in one place. Rather than switching between apps, users will have the ability to see all their information in real-time, in one view – making it easier to make informed dosing decisions to manage their glucose levels. Combined insulin dose and glucose reports can be easily shared with care partners and healthcare professionals as well.

For individuals who prefer automated insulin delivery via an insulin pump, the MiniMed 780G system with Guardian 4 sensor will automatically adjust and correct insulin delivery every 5 minutes with no fingersticks[5]. By pairing the MiniMed 780G system with the recently launched Medtronic Extended infusion set that is indicated for up to 7 days, twice as long as current infusion sets, insulin pump users may need to perform 70 fewer set changes per year[6]. With these two innovations, Medtronic offers the only pump that adjusts and corrects every 5 minutes with an infusion set that lasts twice as long –improving the experience of using insulin pump therapy.

"We know that diabetes is a very personal journey, and we want to meet people where they are with solutions that fit their lifestyle and needs while enabling them to experience seamless support through all their life transitions. That's why we've made the commitment to expand our portfolio and prioritize what matters most to our customers – a technology experience that's easy but doesn't compromise the outcomes they deliver," said Sean Salmon, executive vice president and president of the Diabetes business at Medtronic. "We're pleased to enhance the customer experience through these advancements and look forward to delivering a strong cadence of innovations to eliminate the burden of constant decision making that people with diabetes carry on a daily basis."

In the United States, Guardian 4 sensor and the MiniMed 780G system are investigational use only and not approved for sale.

About the Diabetes Business at Medtronic(www.medtronicdiabetes.com)
Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in approximately 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

[1] If glucose alerts and CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.
[2] Smart insulin pens connect to a mobile app to provide dosing calculations, reminders and CGM system integration.

[3] Guardian™ 4 sensor is the commercial name of "Zeus" sensor in development from Medtronic.

[4] Data may not appear or be delayed in certain instances, including when there is no internet connection. A confirmatory fingerstick is required prior to making adjustments to diabetes therapy.

[5] If glucose alerts and CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. BG needed when SmartGuard™ is first initiated.

[6] Assumes 122 set changes for standard infusion sets and 52 set changes per year for the extended wear infusion set

Contacts:

Pamela Reese Ryan Weispfenning

Public Relations Investor Relations

+1-818-576-3398 +1-763-505-4626

SOURCE Medtronic plc

---

https://news.minimed.com/2021-05-26-Medtronic-Secures-Two-CE-Mark-Approvals-for-Guardian-4-Sensor-for-InPen-MDI-Smart-Insulin-Pen