embecta Announces FDA Clearance of its Disposable Patch Pump for Insulin Delivery Informed by the Unique Needs of People with Type 2 Diabetes

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- *While 9 out of 10 people with diabetes are living with T2D, many of the automated insulin delivery solutions currently on the market were designed for people living with T1D.*
- *300-unit insulin reservoir is more suitable for people with T2D who are interested in moving from multiple daily injections (MDI) to pump therapy, based on an average daily dose of 95.9 units of insulin.[1]*

PARSIPPANY, N.J., Sept. 03, 2024 (GLOBE NEWSWIRE) -- Embecta Corp. ("embecta") (Nasdaq: EMBC), a global diabetes care company with a 100-year legacy in insulin delivery, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its proprietary disposable insulin delivery system. Indicated for adults who require insulin to manage diabetes, including both type 1 (T1D) and type 2 (T2D), the system includes a tubeless patch pump design with a 300-unit insulin reservoir that was informed by feedback from people with T2D and their healthcare providers.

“FDA clearance of our disposable insulin delivery system has been a top strategic priority for our team since launching embecta as an independent company, and achieving this milestone through strong execution exemplifies our commitment to making life better for the growing number of people living with diabetes,” said Dev Kurdikar, CEO. “As we continue to advance toward our vision of a life unlimited by diabetes, our team has focused on developing a patch pump that could address some of the most significant obstacles to adopting pump therapy for people who use insulin daily to manage their diabetes. This platform is also serving as the basis for an automated insulin delivery system in development.”

The system includes a wearable, fully disposable patch pump that provides adjustable basal and bolus insulin for up to three days, depending on the needs of the user. The patch pump features a 300-unit insulin reservoir that accommodates people who have higher daily insulin needs, which is typically true of people with T2D. For such people, the on-market patch pumps may not hold enough insulin to meet their needs for three days.[2] For example, a recent embecta-sponsored study[3] showed that a 300-unit insulin reservoir would meet the needs of 64% of adults with T2D for three-day wear, while a 200-unit reservoir would only meet the needs of 38% of that same population.

In addition to the patch pump, the system comprises a locked-down controller featuring Bluetooth® wireless technology with a color touchscreen designed to create a simplified interface and user experience.

“Our research and development, medical affairs and regulatory teams identified an unmet need within the diabetes community and shepherded this project from concept to clearance with dedication and diligence,” said Dr. Colleen Riley, Chief Technology Officer. “I want to thank the embecta team for their commitment to serving people with diabetes and thank the FDA for their timely review and clearance of a system that has the potential to reduce the burden of managing diabetes for more people and significantly move innovation in this area forward.”

embecta’s patch pump development program also includes plans for a closed-loop version including an insulin-dosing algorithm in a future FDA submission.

References:

[1]Viral Shah, MD, et al, Insulin dosing in U.S. adults with type 2 diabetes (T2D) on multiple daily injections (MDI): A retrospective cohort study

[2]Ekanayake P, Edelman S. Identifying patients with type 2 diabetes who might benefit from insulin pump therapy: Literature review, clinical opportunities, potential benefits and challenges. Diabetes Obes Metab. 2023; 1-18.

[3] Eugene E. Wright, Jr., MD, et al, Evaluating Need for Larger Insulin Reservoir in Patch Pumps: Leveraging Retrospective Dose Data for US Adults with T2D on MDI, https://www.embectamedical.com/pdf/ADA-Poster-1902.pdf

[4] Freckmann G, Buck S, Waldenmaier D, et al. Insulin Pump Therapy for Patients With Type 2 Diabetes Mellitus: Evidence, Current Barriers, and New Technologies. Journal of Diabetes Science and Technology. 2021;15(4):901-915.

About embecta

embecta is a global diabetes care company that is leveraging its 100-year legacy in insulin delivery to empower people with diabetes to live their best life through innovative solutions, partnerships, and the passion of more than 2,000 employees around the globe. For more information, visit embecta.com or follow our social channels on LinkedIn, Facebook, Instagram and X.

Safe Harbor Statement Regarding Forward-Looking Statements

This press release contains express or implied "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 and other securities laws. These forward-looking statements concern embecta’s current expectations regarding its future results from operations, business plans, product performance and impact, and new and anticipated product approvals and launches. These forward-looking statements are

subject to various known and unknown risks, uncertainties and other factors, and you should not rely upon them except as statements of our present intentions and of embecta's present expectations, which may or may not occur. When embecta uses words such as "believes," "expects," "anticipates," "estimates," "plans," "intends", "pursue", "will," "seek," "potentially", "may," or similar expressions, it is making forward-looking statements. For example, embecta is using forward-looking statements when it discusses continuing to invest in its patch pump development program, plans for a closed-loop version, future FDA submissions, and working with the FDA to seek clearance for any of the foregoing. Although embecta believes that its forward-looking statements are based on reasonable assumptions, its expected results may not be achieved, and actual results may differ materially from its expectations. In addition, important factors that could cause actual results to differ from expectations include, among others: (i) embecta's ability to obtain clearance from the FDA of any product; (ii) its ability to market and sell such products successfully; (iii) its ability to anticipate the needs of people with diabetes; (iv) its ability to successfully complete clinical and other trials with favorable results, obtain regulatory clearance and obtain approvals for its products; (v) its ability to manufacture such products in a cost-effective manner, comply with FDA's quality system regulations, obtain appropriate intellectual property protection for such products, gain and maintain market acceptance of such products, secure distribution channels, and obtain access, coverage and reimbursement for such products; (vi) future economic, competitive, reimbursement and regulatory conditions; (vii) litigation; (viii) financial market conditions; (ix) future business decisions made by embecta and its competitors; (x) technological innovations or changes in clinical practice adversely affecting embecta's business; and (xi) the other risks described in embecta's periodic reports filed with the Securities and Exchange Commission, including under the caption "Risk Factors" in its most recent Annual Report on Form 10-K, as further updated by its Quarterly Reports on Form 10-Q it has filed or will file hereafter. Except as required by law, embecta undertakes no obligation to update any forward-looking statements appearing in this press release.

Contacts:

Media
Christian Glazar
Sr. Director, Corporate Communications
908-821-6922
Contact Media Relations

Investors
Pravesh Khandelwal
VP, Head of Investor Relations
551-264-6547
Contact IR