embecta Announces FDA 510(k) Submission for Insulin Patch Pump

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PARSIPPANY, N.J., Jan. 09, 2024 (GLOBE NEWSWIRE) -- Embecta Corp. ("embecta") (Nasdaq: EMBC), a global diabetes care company with a 100-year legacy in insulin delivery, today announced that it has submitted a 510(k) premarket filing to the U.S. Food and Drug Administration (FDA) for a proprietary disposable insulin delivery system.

"This patch pump is intended for people who require insulin to manage diabetes and is informed by the unique needs of people with type 2 diabetes and their healthcare providers," said Colleen Riley, Chief Technology Officer, embecta. "We worked with them to address the needs of those who may require more daily insulin and are looking for a simplified and convenient option for automated insulin delivery that offers the ease of use and discretion of a patch pump, along with a larger 300U insulin reservoir."

"While 9 out of 10 people with diabetes are living with type 2 diabetes, the majority of the automated insulin delivery solutions currently on the market were designed for people living with type 1 diabetes," said Henry Anhalt, D.O., Chief Medical Officer, embecta. "The broader diabetes care community — including clinicians, caregivers, and people living with type 2 diabetes — desires more individualized therapeutic options and tools designed tc lighten the burden of managing diabetes and to improve outcomes for each of the growing number of people living with diabetes."

"Since we became an independent company in April 2022, our team has been working diligently on our priorities, which include investing for growth — notably in the development of a patch pump," said Devdatt (Dev) Kurdikar, Chief Executive Officer of embecta. "The 510(k) submission of our patch pump to the FDA is an important step in the advancement of our strategic priorities, and we look forward to working with the FDA to seek clearance for a product that we believe has the potential to positively impact type 2 diabetes management for many people."

embecta continues to advance its patch pump development program, with plans for a closed-loop version including an insulin-dosing algorithm in a future FDA submission.

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 Twitter.

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," or similar expressions, it is making forward-looking statements. For example, embecta is using forward-looking statements when it discusses continuing to advance 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 trials, obtain regulatory clearance and obtain approvals for its products; (v) its ability to manufacture such products in a cost-effective manner, 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; and (x) 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.

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