

Modular Medical Receives IRB Approval for Pivot Insulin Delivery System Feasibility Study

-Study to Evaluate Usability and Extended Wear for Next-Generation Tubeless Patch Pump

SAN DIEGO, CA / ACCESS Newswire / September 15, 2025 / Modular Medical, Inc. (NASDAQ:MODD) (“Modular Medical” or the “Company”), a leader in innovative insulin delivery technology targeting the \$3 billion adult “almost-pumpers” diabetes market with user-friendly, affordable patch pumps, today announced Institutional Review Board (“IRB”) approval to conduct an in-house feasibility study of its next-generation Pivot insulin delivery system using sterile saline (the “Study”). Pursuant to U.S. Food and Drug Administration (“FDA”) regulations, an IRB is a group that has been formally designated to review and monitor biomedical research involving human subjects. The Study will simulate real-world conditions by delivering sterile saline to adult participants for up to 90 days to gather critical data on device usability, extended wear performance and user feedback.

Modular Medical’s second-generation tubeless platform, its Pivot pump, builds on the Company’s FDA-cleared first-generation patch pump, the MODD1, and aims to continue to enhance accessibility for underserved patients with diabetes and drive market expansion. The insights derived from the Study will be used to refine the Pivot pump ahead of its 510(k) submission to the FDA, which is anticipated in October 2025.

Key objectives and potential impacts of the Study include:

- Assess usability and identify challenges in prolonged wear scenarios;
- Collect participant feedback to optimize design for everyday diabetes management;
and
- Support regulatory pathways, potentially unlocking new markets and revenue streams.

The Pivot insulin delivery system is not currently cleared for sale by the FDA.

“This IRB approval marks another significant milestone in advancing our tubeless insulin pump technology toward market readiness,” said Jeb Besser, CEO of Modular Medical. “By testing extended wear in real-world simulations, we expect to gather invaluable data to make our Pivot pump more intuitive and reliable for adults with diabetes. Once FDA clearance is achieved, we believe our Pivot pump will be well positioned to achieve rapid adoption in the growing wearable diabetes technology sector. This progress underscores our commitment to

innovation, as we look to achieve long-term growth in the expanding diabetes care landscape and bring value to the Company's shareholders."

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to risks, trends and uncertainties that could cause actual results to be materially different from the forward-looking statements contained in this press release, including but not limited to, the timing of the Company's submission of its Pivot product to the FDA; the performance of the Company's products; expected deployments of the Company's pump products to persons with diabetes; the Company's ability to convert patients to use its pump products; the occurrence of future events or circumstances; successful development of Modular Medical's proprietary technologies; whether the market will accept Modular Medical's products and services; anticipated consumer demand for the Company's products; whether Modular Medical can successfully manufacture its products at high volumes; and general economic, industry and political conditions in the United States or internationally; as well as other risk factors and business considerations described in Modular Medical's SEC filings, including its annual report on Form 10-K. Any forward-looking statements in this press release should be evaluated in light of these important risk factors. In addition, any forward-looking statements included in this press release represent Modular Medical's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. Modular Medical assumes no obligation to update these forward-looking statements, except as required by law.

About Modular Medical

Modular Medical, Inc. (Nasdaq: MODD) is a development-stage medical device company that intends to launch the next generation of insulin delivery technology. Using its patented technologies, the Company seeks to eliminate the tradeoff between complexity and efficacy, thereby making top quality insulin delivery both affordable and simple to learn. Its mission is to improve access to the highest standard of glycemic control for people with diabetes taking it beyond "superusers" and providing "diabetes care for the rest of us."

Modular Medical was founded by Paul DiPerna, a seasoned medical device professional and microfluidics engineer. Prior to founding Modular Medical, Mr. DiPerna was the founder (in 2005) of Tandem Diabetes and invented and designed its t:slim insulin pump. More information is available at <https://modular-medical.com>.

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