Capillary Biomedical Receives FDA Approval to Begin Pivotal Trial of its SteadiFlow Seven-Day-Wear Infusion Set Technology

Irvine, CA – January 19, 2022 – Medical device developer Capillary Biomedical, Inc. (CapBio) has announced that it has received investigational device exemption (IDE) approval from the US Food and Drug Administration (FDA) to start a pivotal trial for the assessment of its SteadiFlow seven-day wear infusion set technology.

Infusion sets enable people on insulin pump therapy to deliver insulin under the skin for the maintenance of healthy blood glucose levels. Market research among people with diabetes who pump insulin shows that poor reliability is the #1 problem pump users face today and extending wear duration beyond three days is the most commonly requested improvement.

Capillary's new infusion sets are designed to significantly extend patient wear time to seven days and maintain insulin stability.

For the new study, investigators will recruit at least 240 subjects, aged between 18 and 80, with type 1 diabetes on insulin pump therapy in the 15-site, non-randomized and prospective single arm study. Each participant will undergo 12 one-week wear periods. The study will test Novolog and Humalog insulin. Jaeb Center for Health Research in Tampa, FL will serve as the CRO.

"Current infusion sets are designed to be changed every two to three days, and often fail sooner," said Roy Beck, MD, PhD, director of the Jaeb Center for Health Research. "To have a reliable infusion set that extends wear to a week or beyond would likely improve quality of life for patients on insulin pumps."

CapBio's SteadiSet infusion set, powered by its SteadiFlow technology platform, is designed to increase the wear time of insulin infusion sets by addressing the common causes of infusion site failure. The SteadiSet also features an integrated inserter designed for easy, painless, hidden needle, one-handed insertion. The entire set has been made with materials selected to reduce preservative loss for improved insulin stability and reduced aggregate formation. CapBio's cannula was designed to filter particulates and aggregates before they are delivered to the tissue, which helps to ensure that any aggregates that form in the tubing are removed before reaching the tissue. Reduced aggregates are believed to reduce tissue

inflammation and may help to improve infusion set reliability. The SteadiSet adhesive has also been optimized for extended-wear. The combined features of the SteadiSet infusion set are designed to work together to reduce site failures and increase wear time.

SteadiFlow cannula technology features a soft and flexible cannula designed to move with the body tissue during physical activity, increasing comfort while greatly decreasing tissue damage and inflammation.

"With this pivotal trial we are pleased to be taking a significant next step in the evolution of our SteadiFlow infusion set," said CapBio CEO Paul Strasma. "Based on the strength of previous clinical data, we're optimistic about the results of this forthcoming trial and we're excited to play a leadership role in what might be possible with insulin pump technology."

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Capillary Biomedical, Inc. (CapBio), headquartered in Irvine, California, is focused on simplifying insulin pump therapy to improve the quality of life for people with diabetes. The Company's first product, the SteadiSet™ infusion set featuring SteadiFlow™ technology is designed to improve the comfort, reliability and predictability of insulin pump therapy. Learn more about Capillary Biomedical by visiting www.capillarybio.com.

To obtain illustrations, more information, or to conduct interviews with Capillary principals, contact Paul Williams at paul@medialinecommunications.com or 310/569-0023.