

Capillary Biomedical Reports Best-in-Class Clinical Feasibility Results for its SteadiFlow Seven-Day-Wear Infusion Set Technology at ADA Scientific Sessions

Capillary's trial of extended-wear SteadiFlow technology designed to reduce infusion site failures and improve quality of life for people with diabetes yields highly promising results

Irvine, CA – June 29, 2021 – Medical device developer Capillary Biomedical, Inc. (CapBio) has presented highly favorable clinical feasibility study results for its SteadiFlow cannula technology at this week's American Diabetes Association (ADA) Scientific Sessions meeting.

Results from the study performed at St. Vincent's Hospital in Melbourne, Australia show CapBio's infusion set exceeding performance expectations, with 88% of infusion sets featuring the SteadiFlow cannula technology lasting the intended seven days. The results show a significant improvement over current commercial infusion sets, which have been shown in published studies to last 3-days from 75–85% of the time and 7-days only 33–50% of the time.

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.

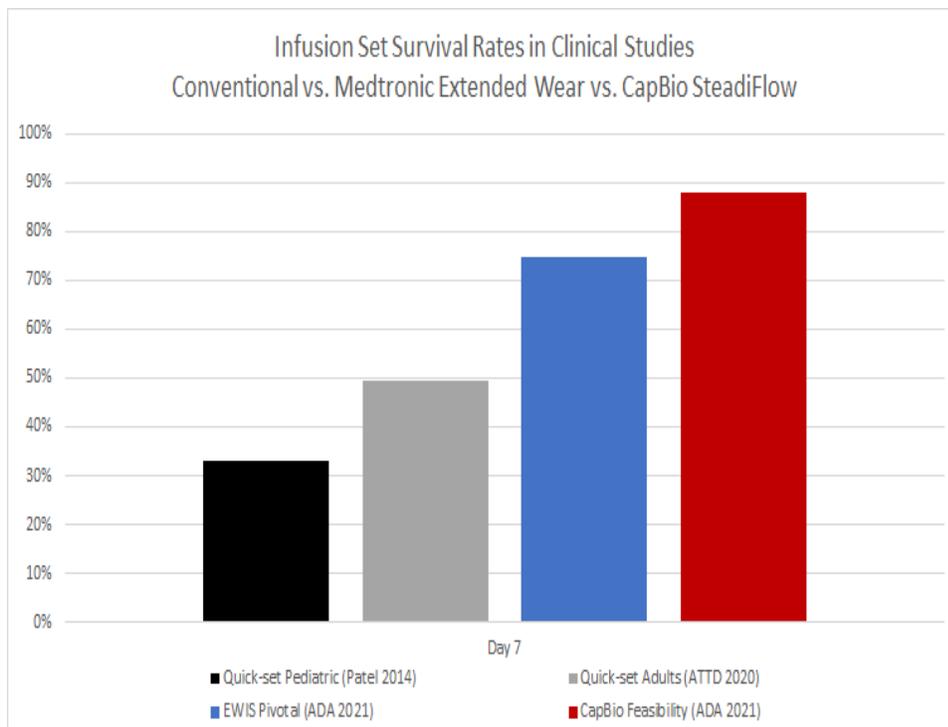
SteadyFlow cannula technology features a soft and flexible cannula designed to move with the body tissue during physical activity, increasing comfort while greatly decreasing tissue damage and inflammation. The cannula features three additional side ports located along the final 6 mm of the cannula length. These additional ports provide redundant delivery paths to reduce the potential for occlusion and spread out the insulin throughout the tissue, which may lead to improved predictability of insulin absorption. The cannula also features an internal reinforcing coil to deliver a kink-proof cannula design aimed at eliminating one of the most common forms of cannula failure. An extra benefit of the reinforcing coil is that it acts as a trap for particles that may form in the tubing or reservoir during delivery, removing the particles before they reach the tissue.

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 designed with materials selected to reduce preservative loss for improved insulin stability and reduced aggregate formation. Reduced aggregates are believed to reduce tissue inflammation and may help to improve infusion set reliability. The SteadiSet adhesive has 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.

For the St. Vincent study, infusion sets featuring SteadiFlow technology were tested with 20 human subjects, who each wore a cannula for three wear periods. Wear periods were for seven days or until set failure – whichever came first. The first wear period was performed as a safety check. The set was used to deliver saline while the subject continued to receive therapy from their own existing pump and infusion set. In the second and third wear periods, infusion sets

with SteadiFlow were used to deliver insulin to the subject. It was discovered that 87.8% of the sets survived for seven days or more with no significant adverse events. There were also no reports of kinked cannulas or occlusion alarms, suggesting the reinforced, flexible cannula design is working as intended to reduce these failure modes.

“Clinical studies into extending infusion set wear initially found that only one-third to half of conventional sets could survive for seven days in real-world conditions,” added CapBio VP of Sales and Marketing, Mark Estes. “Innovations such as Medtronic Diabetes Care’s Extended Wear Infusion Set (EWIS) have increased that to 74.8% survival after one week as reported in their pivotal study results released at this meeting. We’re very encouraged by our clinical data showing that 87.8% of SteadiFlow technology infusion sets survived for seven days. That thirteen percent improvement in survival rate means insulin pump users would experience half the infusion set failures, or twice the reliability, of the next-best infusion set.”



“We are pleased to be able to share such promising news with the audience here at the ADA meeting,” said CapBio CEO Paul Strasma. “Based on the strength of this clinical data and enthusiasm from our current investors and strategic partners, we will be engaging in a structured financing process to secure the capital necessary to conduct a pivotal study of our SteadiSet infusion set, support regulatory clearance and commercialize this best-in-class technology. We’re thrilled to be pushing the envelope of what may be possible with insulin pump technology.”

CapBio’s core cannula technology was developed in part by Professor Jeffrey Joseph of the Sidney Kimmel Medical College at Thomas Jefferson University with support from the National Institutes of Health, the Helmsley Charitable Trust and the JDRF T1D Fund. The company has previously raised over \$20 million from organized angel investment groups and strategic funding partners.

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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.