

Capillary Biomedical Receives \$1.5 Million from Helmsley Charitable Trust for Clinical Trials of New Insulin Infusion Technology

Funding to fuel testing of extended-wear SteadiFlow technology designed to reduce infusion site failures and improve quality of life for people with diabetes

Irvine, CA – October 7, 2020 – Capillary Biomedical, Inc. (CapBio) has announced that it has received a \$1.5 million program-related investment in the form of a loan from The Leona M. and Harry B. Helmsley Charitable Trust (Helmsley). The use of funds includes clinical studies of CapBio's novel SteadiFlow™ technology to evaluate the potential for extended-wear of insulin infusion sets by people with Type 1 diabetes for 7 days and beyond.

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. Infusion sets are a key component of recently introduced automated insulin delivery (AID) systems that use continuous glucose monitoring (CGM) sensors to guide insulin pump therapy. Sets are designed to be changed every two to three days, but sites often fail sooner. Infusion site failures can lead to diabetic ketoacidosis (DKA), hospital admissions, lost days of work or school and other issues that dramatically affect the health, quality of life, and cost for the millions of people with Type 1 diabetes (T1D) worldwide. Infusion site failure is often cited as one of the main reasons people with T1D stop using an insulin pump or AID system, both of which are proven to significantly improve health outcomes for people with T1D.

CapBio's SteadiFlow technology platform features a soft and flexible cannula designed to eliminate kinking and move with the body tissue during physical activity, increasing comfort while greatly decreasing tissue damage and inflammation. The cannula's multiple holes spread out the insulin into more tissue, which clinical studies may show leads to improved predictability of insulin absorption by the body over an extended wear-time. The SteadiSet also features an integrated inserter designed for comfortable cannula insertion with simple one-handed operation. Designed with materials selected for insulin stability and an adhesive optimized for extended-wear, all the features of the SteadiSet infusion set work together to reduce site failures and reliably increase wear time.

“Improving the lives of people with type 1 diabetes is our priority, and CapBio’s work towards developing extended-wear insulin infusion technology holds great promise as we strive to achieve that goal,” said Helmsley Trustee David Panziner. “Diabetes is a 24/7 disease, and insulin is a requirement for survival. Infusion sets are an integral component of insulin pump therapy, and our hope is that CapBio’s extended-wear set will make insulin pump use a more seamless experience.”

The Helmsley program-related investment will support clinical trials to confirm the SteadiSet’s reliability and consistency of insulin absorption for extended-wear. These trials include:

- The completion of a feasibility study with the SteadiFlow cannula technology to demonstrate successful 7-day use in managing T1D;
- The completion of a Pharmacokinetic/Pharmacodynamic (PK/PD) clinical study with SteadiFlow cannula technology to demonstrate how much insulin absorption changes over an extended 7-day use period in commercial Teflon cannulas, and the improvement from SteadiFlow cannulas; and
- A new pilot study centered around SteadiSet infusion sets to demonstrate improved usability and glucose control relative to commercial Teflon infusion sets and evaluate potential for use up to 14 days.

“We are very pleased with the experience people with T1D have reported when using our SteadiFlow technology in the two 7-day clinical trials presently underway,” said CapBio CEO Paul Strasma. “It’s an honor that the Helmsley Charitable Trust is investing to expand the clinical program, allowing us to validate our initial results and push the envelope of what may be possible for our SteadiSet infusion set.”

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 and the JDRF T1D Fund. The company has previously raised over \$10 million of private investment from organized angel investment groups.

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Capillary Biomedical, Inc. (CapBio), headquartered in Irvine, California, 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.

The Leona M. and Harry B. Helmsley Charitable Trust aspires to improve lives by supporting exceptional efforts in the U.S. and around the world in health and select place-based initiatives. Since beginning active grantmaking in 2008, Helmsley has committed more than \$2.5 billion for a wide range of charitable purposes. The Helmsley Type 1 Diabetes Program is one of the largest private foundation funders of T1D in the nation, focused on understanding the disease, developing better treatments, and improving care and access. For more information on Helmsley and its programs, visit www.helmsleytrust.org.

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