EOFlow Receives FDA Breakthrough Device Designation on its Integrated Wearable Automated Insulin Delivery System

SAN JOSE, CA, USA, March 14, 2019 /EINPresswire.com/ -- EOFLOW CO., Ltd., an emerging medical device manufacturer with offices in Seoul, South Korea and San Jose, California, announced today that its closed loop Automated Insulin Delivery /Artificial Pancreas Device (AID/AP), the EOPancreas System, has received Breakthrough Device Designation by the U.S. Food and Drug Administration. The EOPancreas System is designed to provide closed loop blood glucose control for primarily Type 1 Diabetics (T1D) and consists of a novel, integrated wearable, disposable patch containing insulin delivery and continuous glucose monitoring (CGM) subsystems running a clinically- validated closed loop blood glucose control algorithm. The EOPancreas contains a unique, connected architecture, allowing the device to benefit from Artificial Intelligence (AI) algorithms running on a private, validated cloud - termed EOCloud - to allow customization of the closed loop control for each patient. "EOFlow was founded to democratize wearable drug delivery solutions by providing intelligent, connected solutions for patients managing chronic conditions at globally-competitive price points", according to Jesse Kim, founding CEO of EOFlow, "and we see the Breakthrough Device designation as an important validation of our business model."

The EOPancreas System is being developed to address the continuing global challenges associated with diabetes management through lowering the barriers to blood glucose control for subjects living with this chronic condition. According to David Klonoff, M.D., FACP, FRCP (Edin), Fellow AIMBE (Clinical Professor of Medicine, U.C. San Francisco and Editor-in-Chief, Journal of Diabetes Science and Technology), "Recent published results such as those from the T1D Exchange registry(1) emphasize the continuing challenge for achieving target levels of glucose control for patients with Type 1 diabetes. Even with the increasing use of CGM systems, greater improvements in clinically meaningful endpoints, such as Hemoglobin A1c and time in range are needed. Closed loop systems, such as the EOPancreas System, can be attractive tools to improve glycemic control."

Replacing the Expedited Access Program, the Breakthrough Device Program is designed to assist expedited access to the US market for innovative medical device solutions which are intended to treat serious conditions. "The Breakthrough Device designation will assist us in developing clear design and development milestones in concert with the FDA, greatly accelerating our ability to

commercialize this important new technology," says Luis Malave, the president of EOFlow.

About EOFlow Inc.
EOFlow is a wearable medical device company founded in 2011, with offices in Seoul, South Korea and San Jose, California, developing several innovative drug delivery systems based on its proprietary pumping technology. The Company's first product is EOPatch, a fully functional wearable, disposable insulin pump for people with diabetes. For more information please visit us at www.eoflow.com or follow us on Twitter: @EOPatch.

(1) Foster, N.C., R.W. Beck, K.M.. Miller et. al. State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016–2018. DIABETES TECHNOLOGY & THERAPEUTICS. 2019. 21(2): 66-72.

Luis Malave
EOFlow, Inc.
+1 661-644-7539
email us here
Visit us on social media:
Facebook
Twitter
