

EOFlow Receives Approval of Investigational Device Exemption (IDE) Application for its Two-Part Wearable Artificial Pancreas "EOPatch X" for Pivotal Study on People with Type 1 Diabetes in Korea

- ▶ The pivotal clinical study will be conducted at nine leading university hospitals and involve over one hundred people with type 1 diabetes. It aims to obtain statistically significant evidence of efficacy and safety of "EOPatch X"
- ▶ "EOPatch X" is a two-part wearable artificial pancreas (AP) solution that automatically adjusts basal insulin delivery based on the user's glucose level

EOFlow Co., Ltd. (KOSDAQ: 294090) (EOFlow or the Company), a provider of wearable drug delivery solutions, has announced that the Company received from Ministry of Food and Drug Safety of Korea (KMFDS) approval of Investigational Device Exemption (IDE) application for its two-part wearable artificial pancreas "EOPatch X" and will soon begin pivotal clinical study on people with type 1 diabetes in Korea.

The pivotal study is a multicenter trial that will be conducted at nine university-hospitals and will enroll over one hundred people with type 1 diabetes. It aims to validate the clinical efficacy and safety of EOPatch for treating people with type 1 diabetes. It is known to be the first pivotal clinical trial of artificial pancreas based on wearable insulin pump therapy for type 1 diabetes in Korea. This study is supported with Korean government research grants.

In the immediate term, the Company is focused on obtaining the Institutional Review Board (IRB) approval from each hospital. Upon obtaining Institutional Review Board (IRB) approvals, EOFlow expects to commence clinical trial around January 2022 and complete them by December 2022. Upon successful completion of the pivotal clinical trial, the Company intends to obtain medical device market approval from KMFDS.

'EOPatch X' is a two-part wearable artificial pancreas (AP¹) solution that automatically adjusts basal insulin delivery based on the user's glucose level. 'EOPatch X' links its wearable pump 'EOPatch', which runs an AP algorithm, to a separate (third party) continuous glucose monitoring (CGM) sensor. This solution greatly increases user convenience by eliminating the need to check the blood glucose level as well as the need to monitor and adjust basal insulin delivery throughout the day. The user is still expected to program and deliver a meal bolus when needed, per the amount of carbohydrate intake.

¹ Also known as automated insulin delivery (AID)



Currently, there are only two AP solutions commercially available in the world -- both are based on durable insulin pumps. Since their market introduction, the number of users has increased significantly, despite considerable user inconvenience associated with durable pumps. Wearable pumps without infusion lines are the next-generation AP solution, but currently none has yet received regulatory approval for market introduction. Based on market demand for AP solutions indicated by demand for currently available AP solutions, when "EOPatch X" is commercialized, high growth in sales is expected.

According to EOFlow's founder CEO Jesse J. Kim, "We expect to obtain significant and meaningful clinical data by the end of year 2022 and commercialize 'EOPatch X' by the end of year 2023. Based on this pivotal clinical trial, we intend to demonstrate and validate efficacy and safety of therapy using EOPatch for people with type 1 diabetes, improving quality of life for them."

CEO Jesse J. Kim added, "Based on the clinical results, we will make every effort to commercialize products in regions where demand for wearable artificial pancreas is great such as the United States and Europe to increase our sales growth."

EOFlow's EOPatch is Korea's first (and the world's second) tubeless, wearable, and disposable insulin pump. It makes possible continuous subcutaneous insulin infusion (CSII) for people with insulin dependent type 1 and 2 diabetes. EOFlow recently announced a supply contract worth about 45.3 billion Korean won with PT. Prasasti Nusantara Sukses (PT. PNS) of Indonesia. With Indonesia as a base, the Company plans to expand into the ASEAN market in earnest. Export negotiations are also underway in various regions such as China, the Middle East, and South America.