Press Release
Paris, January 7th, 2021

Diabeloop SA. and SFC Fluidics Inc. announce development agreement for the United States

SFC Fluidics Inc., developer of an Alternate Controller Enabled (ACE) insulin delivery pod and Diabeloop, pioneer in therapeutic artificial intelligence, are partnering to integrate the SFC ACE insulin pod into Diabeloop's Automated Insulin Delivery (AID) solution. The agreement includes a full US-adaptation of the system.

A common mission: bring the next generation of diabetes management to patients with type 1 diabetes in the United States.

Diabeloop is developing interoperable solutions, based on a proprietary self-learning algorithm, for diabetes management. Both DBLG1®, their first product, and DBL-hu (for highly unstable Type 1 diabetes) have received CE-marking and will be deployed in Europe in 2021.

The technology developed by Diabeloop - an algorithm hosted in a dedicated handset – wirelessly communicates with a continuous glucose monitoring device (CGM) and an insulin pump in an AID (closed-loop) system. Diabeloop's artificial intelligence analyzes glucose data, calculates the proper dose of insulin to be administered and instructs the pump to deliver it, thus automating the treatment.

The agreement signed today covers the development of a system integrating the SFC insulin pump as an Alternate Controller-Enabled[1] (ACE) insulin pump.

SFC's ACE insulin delivery pod ("Panda™") is intended for the subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. Its advanced microfluidic pumping system (ePump®) is designed to provide accurate delivery of extremely small doses of insulin without the resolution limits inherent in other commercially-available delivery devices. SFC believes its technology will effectively eliminate 95% of over and under dispenses of insulin. SFC's proprietary Dispense Confirmation Sensor (DCS™) represents a differentiating technology that can detect flow or no flow conditions of insulin in real-time. The DCS will quickly signal a lack of dispense for any reason. SFC received the US Food and Drug Administration's breakthrough device designation for its Panda™ insulin delivery pod on November 5, 2020.

"We are encouraged that our relationship with Diabeloop continues to progress towards a meaningful goal of a marketed artificial pancreas in the US", commented **Don Jackson, CFO of SFC**.

A fully integrated AID system tailored to the US market

Diabeloop and SFC Fluidics share the vision of advancing diabetes therapy for patients through state-of-the-art technologies and a fully automated approach.

SFC Fluidics and Diabeloop continue their relationship, which started with a project initially funded by the JDRF.

"JDRF is committed to improving the lives of people with type 1 diabetes by supporting innovations in diabetes treatments. We are excited to see the partnership between Diabeloop and SFC Fluidics continue to flourish and look forward to the development of a novel artificial pancreas system that can improve the health and quality of life of people living with T1D", said **Jonathan Rosen**, Ph.D., Associate **Director of Research at JDRF.**

SFC would also like to acknowledge the National Institutes of Health, including the National Institute of Diabetes and Digestive and Kidney Diseases, for help in funding the development of various aspects of the ACE pod[2].

The new agreement includes the adaptation of Diabeloop's algorithm and data visualization platform YourLoops™, the integration of the SFC ACE insulin pump, as well as the application for regulatory approval and the conduct of non-clinical and clinical trials, all following US Food and Drug Administration regulations[3].

"We are delighted to reinforce our collaboration with this strong partner. The conclusion of this agreement with SFC Fluidics, Inc. is a real mutual achievement, and for Diabeloop it is an additional opportunity to enter the US market ", commented **Marc Julien, co-CEO of Diabeloop**.

About Diabeloop

Diabeloop's mission: to relieve people living with Type 1 diabetes from dozens of therapeutic decisions and reduce their heavy mental burden. Initially conceived from a medical research project, Diabeloop was created in 2015 by Dr. Guillaume Charpentier, now Chief Medical Officer, and Erik Huneker who has co-managed the company with Marc Julien since 2016. This complementary management team works with experienced partners, CEA-Leti (a research laboratory) and CERITD (a French research team of diabetologists).

In 2018, DBLG1® System, Diabeloop's first medical device for automated diabetes management, obtained CE marking, followed by DBL-hu, its solution for highly unstable Type 1 diabetes management in 2020.

A second round of financing of 31 million euros concluded in November 2019 to speed up the international commercial rollout of the DBLG1® iController and support an ambitious R&D program.

Today, Diabeloop gathers the personality, the passion and the skills of close to 100 talented individuals who work hard to improve the quality of life for every person living with Type 1 diabetes.

About SFC Fluidics, Inc.

SFC Fluidics, Inc. has a mission to advance healthcare and improve quality of life through our enabling microfluidic technologies. The company's vision is to become a recognized global leader in drug delivery, with a focus on insulin, where our unique product lines improve lifestyle and affordability. SFC Fluidics® is a VIC

Technology Venture Development™ portfolio company. For more information, please visit sfc-fluidics.com or follow us on Twitter: @sfcfluidics.

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[1] FDA NEWS RELEASE: FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices

[2]The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

[3]+ ISO13485 and other laws and regulations related to insulin pump

DBLG1 is a medical device of Diabeloop for the treatment of type 1 diabetes in adults. This device is intended for use by a single patient and requires a prescription. For complete information on use and safety information, see the user manual. Diagnosis and information about your treatment should be discussed with your physician. This medical device is a regulated health product which carries, under this regulation, the CE marking.

DBL-hu is a Diabeloop medical device for the treatment of highly unstable type 1 diabetes in adults. This device is intended for use by a single patient and requires a prescription. For complete information on use and safety information, see the user manual. Diagnosis and treatment information should be discussed with your physician. This medical device is a regulated health product and is CE marked under these regulations.

None of the devices mentioned are FDA approved.

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