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## Diabeloop obtains CE mark for hybrid closed loop, plans to launch in France in early 2019; Kicking off new round of funding - November 9, 2018

*Launching "DBLG1" system with Kaleido patch pump, locked-down Android controller, and Dexcom G6 (requiring CE mark update); Second AID system to EU market behind Medtronic; Round will support FDA submission*

Diabeloop announced this morning that it has received CE marking for its hybrid closed loop system ("DBLG1"), which we learned [at DiabetesMine](#) will launch with the Kaleido patch pump (what's that? here's our take on Kaleido from [EASD 2015](#) and [2016](#) and [2017](#) as well as [CES 2017](#)), Diabeloop's locked-down Android controller, and Dexcom G6.

Management expects a gradual launch in France early next year to align with availability of Dexcom's G6 (an update to the existing CE Mark is required) ahead of broader scaling in 2Q19. This is a delay from the end of 2018 launch plan, but a great move to launch with G6. Giving users the option to use a Cellnovo patch pump in the system is on the "roadmap."

Diabeloop will start with some "selected centers" in France, potentially also including other geographies where physician demand for the system is high. We last heard the system would also launch in the Netherlands and Sweden in 2018, although management is currently in the process of "re-evaluating" which markets to enter after France, particularly seeking countries in which there is an appetite for innovative medical devices and fluid reimbursement mechanisms exist.

The algorithm is not embedded in the pump, so if the Android handheld is out of range for more than 25 minutes, the pump reverts back to a reference basal rate. Users can adjust the algorithm target between 100-130 mg/dl, a big advantage over 670G. **There is also a "Zen mode," which "virtually ensures" hypoglycemia avoidance over a short time period** - cool! Remarkably, ~75% of users stop counting carbs with the system, presumably doing more qualitative meal announcement.

We saw 12-week home data from the system [at ADA](#), headlined by a 2 hr/day increase in time between 70-180 mg/dl (67%) vs. open loop (59%). Adjusted for baseline A1c, the closed-loop group spent 50 minutes less per day <70 mg/dl (1.6% vs. 4.9%), 10 minutes less per day <50 mg/dl (from a low base; 0.1% vs. 0.8%), and 30 minutes less per day >300 mg/dl (2.6% vs. 4.5%).

Depending on geographic cadences for Medtronic and Tandem, Diabeloop is likely to be the second hybrid closed loop system to market in most EU countries - it could feasibly be first in France. Medtronic has [officially initiated](#) its OUS 670G launch in geographies such as the UK, Belgium, and Spain. For Tandem's part, respective launches of Basal-IQ and Control-IQ (both with Dexcom G6) [are expected](#) in "early 2019" and ~2020. Diabeloop takes numerous calls per day from patients expressing interest in getting on DBLG1, and we're excited to see hear the market's feedback given the strong clinical data. Obviously Diabeloop will face larger companies with more commercial experience, and there is some risk to partnering with two small, slow-to-ramp pump manufacturers.

As we noted at DiabetesMine, the Diabeloop team is ~55 people, and the algorithm has been tested for over 6,000 patient-days and presented in 34 orals/abstracts/papers (most recently [at ADA](#)).

- **Diabeloop is also seeking a new round of funding, looking to build on the impressively slim 13.5 million euros (~\$15.6 million) raised to date - presumably not much is left.** The round will reportedly go toward scaling and R&D (Diabeloop is already working on "DBLG2") and will be "significantly more" than the last round of financing - if all goes as planned. Diabeloop expects to complete funding and scale to more countries in 2Q19. Somewhat ambitiously, management hopes to raise enough to launch in the EU, achieve pediatric approval, submit to the

FDA, and support the preliminary market introduction in the US. Diabeloop aims to attract new investors alongside existing ones.

- **We wonder if Diabeloop will consider changing the name from "DBLG1" to something more aspirational, or at least, more memorable.**

HOW DOES THE DBLG1 SYSTEM WORK ?



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