

Diabeloop launches CE Mark Pivotal Trial with Cellnovo pump; results expected by end of 2017, filing and launch expected in 2018 - April 24, 2017

On Thursday, Cellnovo [announced](#) that its partner Diabeloop has launched a [CE Mark pivotal trial](#) of the Diabeloop Artificial Pancreas. The three-month study will compare the Diabeloop hybrid closed-loop algorithm running on a dedicated Android phone + Cellnovo pump + Dexcom CGM vs. open-loop therapy using "other insulin pumps" + CGM. The crossover study, [posted here on ClinicalTrials.gov](#), will enroll 60 patients (18+years) at 12 centers in France, with results expected by the end of 2017. A CE Mark filing and launch is expected in 2018, allowing Diabeloop to commercialize the system (of which Cellnovo is the pump component). This trial is still listed as "not yet recruiting" [on ClinicalTrials.gov](#).

We saw initial three-day results from Diabeloop [at ATTD 2017](#), where the system showed very encouraging efficacy in the context of meals and exercise (80%+ time-in-range). The CGM is not specified in the press release, but the [trial page](#) says it will use Dexcom; perhaps commercial negotiations are still ongoing. Diabeloop plans to pursue a monthly service model for automated insulin delivery, similar to Bigfoot's plan.

This news quickly follows Cellnovo's [move last week](#) to license TypeZero's Artificial Pancreas technology, with a launch also expected in 2018 (EU first). Now, Cellnovo has two commercial paths to automate insulin delivery - a component in Diabeloop's system and its own system with TypeZero - and CEO Sophie Baratte told us there are two reasons why: (i) "to guarantee that Cellnovo's system is included in a product that will be available as soon as 2018"; and (ii) in the spirit of providing the best solutions to patients.

As we noted [last week](#), Cellnovo will need excellent execution on the regulatory, reimbursement, manufacturing, and management fronts to get one or both systems to market by next year. We're glad to see it pursuing multiple commercial paths, which should help de-risk the process.

- **Regarding the [Cellnovo-TypeZero product](#), management shared the following updates with us following our article last week:** (i) a joint pivotal study is being planned to support Cellnovo-TypeZero approval in both the EU and US, and this will be separate from the International Diabetes Closed Loop study; (ii) Cellnovo-TypeZero intend to launch in Europe first in 2018, with the US following "shortly after"; (iii) the TypeZero algorithm and application will be built into the Cellnovo controller, and if the controller is out of range, the patient will leave closed loop (unlike Insulet's OmniPod Horizon or Bigfoot's system); and (v) Cellnovo's commercial CGM relationship is "still in negotiations" (we assume Dexcom).

Close Concerns Questions

Q: Between Diabeloop-Cellnovo and Cellnovo-TypeZero, which is more likely to come to market? Which has more risk? If both systems come to market, how will they coexist?

Q: How will Diabeloop-Cellnovo compare to Cellnovo-TypeZero in terms of efficacy, user experience, form factor, cost/business model, etc.

Q: Assuming Dexcom is the commercial CGM partner, what is taking so long to reach an agreement? (Bigfoot has also shared this as a concern; [see here](#).)

-- by Adam Brown and Kelly Close