

## Beta Bionics brings machine learning to insulin delivery



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### Can a device control a patient's blood sugar based on bodyweight alone?

The match-up of Senseonics and Beta Bionics could mean the development of an artificial pancreas system unlike anything else, employing the former's implanted glucose sensor and what the latter calls its bionic pancreas. The goal is for the system to teach itself, rather than requiring the patient to enter various data manually at regular intervals.

"Ours is a system that is fully autonomous at all times, so there is no user input that requires carbohydrate counting or determining basal rates," says Edward Raskin, vice-president of business development at Beta Bionics. But the system has not entered the clinic yet, and even Beta Bionics's lead asset, a collaboration with Dexcom, has yet to start its pivotal trial.

Beta Bionics is responsible for the insulin pump end of the various artificial pancreas systems it is investigating. Its device is called the iLet, and is a dual-chamber pump that is eventually intended to deliver both insulin and glucagon, to provide therapy for hypo as well as hyperglycaemia. Beyond that, a glucagon-only system is envisioned, to treat patients with congenital hyperinsulinism and other disorders of chronic low blood sugar.

The versions of the iLet – the name is of course a pun on islets of Langerhans, the regions of the pancreas that contain insulin-producing cells – in current development only deliver insulin, however. When used in tandem with a continuous glucose monitor (CGM) the iLet is intended to run with no input from the user.

"You simply enter bodyweight and the machine-learning algorithms determine what the appropriate dose of drug is every five minutes," says Mr Raskin. The device can correct for all the other parameters, such as food intake and the patient's age and level of physical fitness.

"Patients aged six all the way up to 80, teenagers that consume massive amounts of calories and are engaged in growing and hormonal changes, female monthly cycles, are all accounted for as the system begins to learn and comes to know the patient," Mr Raskin says.

This is a contrast to devices available today. For instance Medtronic's 670G, generally regarded as the most advanced artificial pancreas-type system on the market, requires the user to tell it how much carbohydrate they have eaten and calculate and administer mealtime boluses, even when it is in "auto" mode.

### Pipeline

If this month's deal with Senseonics carries the potential for a truly innovative artificial pancreas, the choice of Dexcom as a partner is sensible for Beta Bionics's first steps towards the market.

Dexcom has launched a CGM advanced enough not to require finger stick calibration, the G6, although it is the earlier G5 that is used in Beta Bionics's research. This project is about to start a US trial with the FDA's buy-in. The multicentre, multi-arm, crossover study will assess the system in a home use setting, and will enrol adults and children aged over six who have type 1 diabetes.

The device will deliver Novo Nordisk's recently approved fast-acting insulin Fiasp. Should all go well, pivotal trials with the final iLet design ought to begin in 2019 with a PMA filing the same year, and the device could be launched in 2020.

The design of a pivotal trial is not yet clear, but Medtronic's 670G had to show a significant decrease in patients' mean haemoglobin A1c after three months' use as the primary endpoint in its 124-patient US approval study ([Medtronic gets closer to an artificial pancreas, June 14, 2016](#)).

As for the bihormonal system, this stands a chance of being the first such product to reach market, Mr Raskin says. "There are currently none that have been approved. Ours is the first-in-class, first-of-its-kind system. Our first-to-market device will be our insulin-only product, and we expect to follow with the additional glucagon analogue in approximately 2022."

#### Selected ongoing trials of Beta Bionics's bionic pancreas systems

Decription	Patients	ID	Results expected
Set-Point: complex, crossover trial assessing various configurations of insulin-only and bihormonal bionic pancreas	132 adults with T1D or T2D	NCT02509065	2018
Pilot study of bihormonal bionic pancreas in patients with hyperinsulinism who developed diabetes after pancreatectomy	10 patients aged 6-30	NCT03303196	2020
Randomised crossover trial of insulin-only bionic pancreas with different rapid insulin analogues (Humalog, Novolog, or BioChaperone lispro)	20 adults with T1D	NCT03262116	2020
Randomised comparison of bihormonal and insulin-only bionic pancreas in exercising patients	40 adults with T1D	NCT03217175	2020
Set-Point Study for type 2 diabetes (SPT2D): insulin-only bionic pancreas vs normal care	20 adults with T2D	NCT03552523	2020
Feasibility trial of bihormonal bionic pancreas in cystic fibrosis-related diabetes	129 adults with cystic fibrosis-related diabetes	NCT03258853	2022

The collaboration with Senseonics on an insulin-only device might take a little longer to reach fruition, with companies currently working on making their respective technologies compatible. Eversense, Senseonics' implanted glucose meter, is not yet approved in the US, but it scored a flawless adcom vote in March so this milestone cannot be far away.

"The Senseonics platform is highly attractive because it's a different form factor - it's an implantable," says Mr Raskin, pointing out that some patients cannot wear, or do not want to wear, a Dexcom CGM. Financial terms were not disclosed, though Mr Raskin did say that there were some "relatively minor" shared development costs as part of the agreement.

#### More cash

What Beta Bionics is trying to do is incredibly difficult. A system to control a patient's blood sugar with nothing more to go on than that patient's bodyweight requires not just reacting instantly to blood glucose readings but, since insulin takes time to have an effect, actually predicting the sugar level ahead of time.

No other company has even come close to this kind of advance, though many are trying. Even so, several other diabetes players believe in Beta Bionics - its investors include Novo Nordisk, Lilly and Zealand Pharma. Zealand's dasiglucagon is to be used in the dual-chamber system.

Beta Bionics is raising more money in a B round, Mr Raskin says. With a pipeline of different devices and collaborations galore, it will find plenty of uses for its cash.

