

DISRUPTS 2.2B DIABETES MARKET

Novel Cellnovo pump leading race for future of insulin delivery

By John Brosky, Contributing Writer

PARIS — Edging out international giants, a Franco-Anglo start-up won the pole position in the race for the future of insulin delivery when its novel wearable device was selected for the upcoming International Diabetes Closed Loop Trial (IDCL) in the U.S.

“We shipped 224 kits by end of last year, so obviously this makes us a very small player,” said Sophie Baratte, the CEO of Cellnovo Group SA, which is based in Paris with operations in Swansea, Wales in the U.K. “Yet our insulin pump is now in the leading program for the artificial pancreas, and you can’t get better than that,” she told *Medical Device Daily*.

Funded by the National Institutes of Health (NIH) the goal of the IDCL trial is to demonstrate that Type 1 diabetes can be controlled using an artificial pancreas, so called because it is a wearable system to automate insulin delivery by combining a continuous glucose monitor (CGM) with an insulin pump.

The trial is being conducted by Typezero Technologies LLC of Charlottesville, Va. and the Head of Patient Engagement there, Molly McElwee-Malloy, told *Medical Device Daily*, “We will be testing other pumps in addition to the Cellnovo insulin pump. We have previously worked with multiple pumps and plan to continue those relationships.”

To this point, only the agreement with Cellnovo has been announced for the IDCL trial, which is being closely followed by the international diabetes community, most recently in discussions at the Advanced Technologies & Treatments for Diabetes conference this month in Milan, Italy.

The IDCL trial is not the only artificial pancreas program underway, but it is the most advanced and has the highest profile, which is why the announcement raised eyebrows that Cellnovo is the insulin pump of choice for the study. (*Medical Device Daily*, Feb. 8, 2016.)

Positive outcomes for this artificial pancreas system could prove disruptive in an insulin pump market that a leading player, Medtronic plc, estimated is north of US\$2.2 billion annually.

The Cellnovo pump was selected for the IDCL trial for innovative features that include e-connectivity, the wearability of the micro-pump, the precision of insulin delivery, and a low-cost, single use insulin reservoir that detaches from the pump.

Among the participants in the IDCL trial, only those with the Cellnovo pump will be able to read in real time the insulin required by their metabolism was actually delivered by the pump. The data can also be viewed and acted upon by the patient’s care team in real time.

All other pumps require the user to attach a USB cable at regular intervals, often weekly, to upload and send insulin delivery data.

Other trial participants will be trailing a thin plastic tube from a pump device strapped to their body running under clothing to the needle insertion point.

CELLNOVA OFFERS CRITICAL MINIATURIZATION

The smaller, lighter Cellnovo pump uses a patch-delivery method, though this is not to be confused with a transdermal drug delivery method, as there is a micro-needle mounted on the pump that pierces the dermis for a subcutaneous delivery of insulin.

“This wearable pump fits exactly with the idea of an artificial organ because it frees the person from the burden of their disease, frees them from the therapy because everything is automated. No one is asking the patient to download data, so compliance goes away as an issue,” said Baratte.

The key innovation in the Cellnovo pump that has allowed a miniaturization of the components and the low-cost, disposable insulin reservoir is the microfluidics, built around a micro-actuator that is a piston with no moving parts and driven by the expansion and contraction of paraffin wax against a membrane using ultra low-energy heating.

The micro-pump has demonstrated a highly accurate drop-by-drop controlled delivery of insulin, Baratte said, adding that a study from Cardiff University in Wales demonstrating superiority in delivery for the device is currently being reviewed for publication.

Taking a lead position in the state-of-the-art IDCL trial, Baratte said, “means that when the market is ready to accept the artificial pancreas for insulin delivery, we will be one of the players.”

Meanwhile, she said, “this put us in a collaboration with

©2016. REPRINTED WITH PERMISSION FROM THOMSON REUTERS.



teams that are at the top of their game, allows us to interact with some very clever people for problem solving in areas from insulin delivery to artificial intelligence and everything in between. This could help us move to next-generation features derived from high level research.”

The IDCL trial builds on the Typezero Incontrol artificial pancreas system, a commercialized version of an algorithm for insulin delivery system developed at the University of Virginia in Charlottesville.

In addition to the University of Virginia, the Typezero artificial pancreas will be tested at other academic medical centers sites, including Harvard University, the Mayo Clinic, Mount Sinai School of Medicine, Stanford University, the University of Montpellier in France, the University of Padova in Italy and the Academic Medical Center at the University of Amsterdam in the Netherlands.

The study will randomize 240 people with Type 1 diabetes two-to-one against the standard of care where patients manually monitor and control insulin levels using a CGM and a standard pump.

The IDCL test cohort of 80 patients will receive the Incontrol system loaded on a smart phone, a CGM from Dexcom Inc., of San Diego, and the insulin pump.

Among the roughly 3.5 million people in North America

and Europe with Type 1 diabetes, insulin pumps are used by roughly 27 percent of patients in North America and 10 percent in Europe, according to a Cellnovo estimate. The majority of Type 1 patients manually inject insulin several times each day.

In addition to Medtronic, other players competing for market share and greater penetration for insulin pumps include F. Hoffmann-La Roche AG, and Animas Corp., a division of Johnson & Johnson Inc., and the fast-growing Tandem Diabetes Care Inc.

While Cellnovo is a fresh entrant, it is backed by Paris-based Air Liquide SA, which has identified diabetes as a growth area for extending its international footprint in home care that currently is focused around chronic respiratory diseases.

For Cellnovo's IPO on the Euronext Paris exchange in 2015, Air Liquide took the maximum position allowed of nearly 5 percent of shares.

Named Cellnovo CEO in October 2015, Baratte said she took over a company constrained by its capacity to produce the innovative new insulin pump.

Her immediate focus is to complete a technology transfer to Singapore-based Flextronics International Ltd. that will enable a mass production of the pump.

She said in 2016 Cellnovo will also file an FDA 510(k) submission and expects a CE marking for a second-generation patient interface device.