

BioCentury

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Product Development

To the rescue

By Michael Flanagan
Senior Writer

Hypoglycemia is the most common side effect of insulin treatment and can result in seizures, unconsciousness and death. Administering glucagon reverses hypoglycemia by facilitating the release of glucose into the bloodstream. Yet, according to **Enject Inc.**, only 900,000 glucagon rescue kits are sold annually in the U.S., where there are 1.4 million Type I diabetics who should have at least one rescue product on hand.

Moreover, the two glucagon rescue products marketed in the U.S. have a total of \$70 million in sales. Enject is betting that a safer, more convenient product can grow the market to \$200 million or more, and is aiming to bring its GlucaPen glucagon autoinjector to market as early as fall 2010.

Glucagon cannot be premixed, because it breaks down within an hour of reconstitution. Thus the two approved products, one from **Eli Lilly and Co.** and the other from **Novo Nordisk A/S**, are kits that require a patient or caregiver to mix the solution under emergency conditions. This requires injecting diluent from a prefilled syringe into a vial containing dry glucagon, shaking to mix, then withdrawing the solution using the same syringe, and finally injecting it into the leg or abdomen.

"This is an outmoded system, which led us to wonder why nobody had done a pen product," said Chairman Daniel Green.

GlucaPen combines a dual-chamber cartridge exclusively licensed from **Vetter Pharma-Fertigung GmbH & Co. KG** and a pre-attached needle design exclusively licensed from **Scandinavian Health Ltd.** The dual chambers keep the diluent and glucagon separated until injection, and the pre-

attached needle reduces the risk of bending or breaking the needle, or of caregivers sticking themselves accidentally.

"All the person administering needs to do is press the shield guarding the needle against the skin to trigger an automatic injection within five seconds, and the shield locks back into place after you withdraw the device," said Green.

Green was founding president and CEO of now-defunct diabetes company DiObex Inc., where he and Richard Rylander "presented an earlier version of the GlucaPen concept to our board, but the VCs didn't think that it was a big enough opportunity," he said.

Rylander, who is now president and CEO of Enject, told BioCentury the company completed a pair of online surveys this month, which he said "show that

there is a clear desire from patients and, in particular, from their caregivers for a pen product versus the syringe and vial kits now available."

Enject hopes to submit the survey results for publication in the coming months, but more importantly hopes to use them to help attract a partner.

Were Enject to partner with the likes of Lilly or Novo, which each market a recombinant glucagon, the partner's approved molecule would likely be incorporated into GlucaPen, and the resulting product would be considered a line extension that could get to market as early as fall 2010, according to Green.

The alternative would involve licensing non-exclusive rights to use a synthetic glucagon manufactured by **Bachem AG**, which would require submission of an NDA under section 505(b)(2) of the Food, Drug and Cosmetic Act and would push

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launch out a year. Bachem's product, which Rylander said is the only API manufactured to cGMP standards, is approved in Japan.

Either way, Enject expects to be ahead of potential competitors developing glucagon products that are stable in solution. **Marcadia Biotech Inc.**'s MAR510, a glucagon analog that is stable in solution, is slated to begin Phase I testing this year.

Christine Van Marter, a spokesperson for Lilly, said the pharma is also investigating next-generation molecules and technologies for delivering glucagon, but nothing is in the clinic.

Enject has raised \$2.5 million in a series A round through individual investors and expects it will need only another \$7.2 million to complete submissions of the necessary regulatory applications, which will include a 510(k) application for the pen device.

Green expects to be able to grow the glucagon rescue market based on premium pricing and increased demand for a safer and simpler product.

"These are products that haven't been promoted in a long time, so taking into account the typical annual growth, plus a price premium, the true market opportunity for the U.S. alone is north of \$200 million," he said.

"Assuming we can make a deal that works for our investors" then Enject would be open to a sale of the company, noted Rylander. However, "if we think the value can be increased by pursuing the commercialization ourselves then we might consider folding other opportunities into the mix."

COMPANIES AND INSTITUTIONS MENTIONED

Bachem AG, Bubendorf, Switzerland

Eli Lilly and Co. (NYSE:LLY), Indianapolis, Ind.

Enject Inc., Battle Ground, Wash.

Marcadia Biotech Inc., Carmel, Ind.

Novo Nordisk A/S (CSE:NVO; NYSE:NVO), Bagsvaerd, Denmark

Scandinavian Health Ltd., Taoyuan, Taiwan

Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany