

After decades of work, Diasome's insulin additive enters 200 patient trial

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More than 30 years ago, Dr. Blair Geho started hunting for a way to improve insulin.

Now his life's work is being put to the test in a clinical trial that will involve up to 200 patients with type 1 diabetes.

Through Diasome Pharmaceuticals, he and his son, Robert, are working to commercialize an insulin additive designed to help diabetes patients gain more control over their blood sugar level — something they've struggled with since injected insulin was first used in 1922.

If the current Phase IIb trial produces strong data, the product still would have to pass a larger Phase III trial before hitting the market. But the Gehos would be one step closer to achieving a goal Blair began pursuing after reading a 1972 research paper that pointed out the limitations of insulin injections.

“Several people said, ‘If you really want to fix something, figure out how to fix insulin,’ ” he said.

What's wrong with insulin?

In a healthy patient, the pancreas delivers insulin directly into the liver — which serves as a “glucose storage tank” for the body, said Robert Geho, CEO of the company, which is based at the Global Cardiovascular Innovation Center near the Cleveland Clinic.

When diabetes patients are injected with insulin, it helps them process sugar throughout the body, but not much of the insulin gets to the liver, he said.

The additive is meant to fix that problem. It consists of Frisbee-shaped molecules with an electromagnetic charge that gives them the ability to hold onto insulin molecules. The additive then carries the insulin molecules to the liver, where they can more effectively regulate the patient's blood sugar, the Gehos said.

To back up their point, the Gehos presented data from a few smaller trials. For instance, in one study, nine type 1 patients tested out regular insulin and insulin with the additive at different times. When the additive was included,

their peak peripheral blood glucose level was nearly 40% lower, according to a study published by the Journal of Diabetes and its Complications in 2001.

They presented graphs from two other studies — one involving dogs and another unpublished study involving humans — that also showed a significant impact. They've conducted a total of 18 human trials, but many of them tested different versions of the drug on patients with type 1 and type 2 diabetes.

Some of the studies began long before Diasome was founded in 2004. So what took the company so long to get to this point?

For one, Diasome spent several years testing an oral version of the drug geared toward type 2 diabetes patients. In 2012, however, the company's board decided to pursue an injectable version designed for type 1 patients. The board also promoted Robert Geho to CEO, replacing Len Rosenberg, an executive from the Philadelphia area.

Geho noted that there's greater need for better type 1 diabetes treatments. He also said that it's cheaper and simpler to commercialize an injectable insulin additive.

He added that awareness of the need for improved diabetes treatments "dramatically changed over the last five years."

"2012 for Diasome really represented a tipping point," he said.

Diasome has raised a total of \$25 million from investors. More than \$5 million came from McDonald Partners, a brokerage and investment advisory firm in Cleveland.

The firm's CEO, Tom McDonald, met Blair Geho in 2013 while serving on two visiting committees at Case Western Reserve University. Geho serves as a chief translational officer at the university's school of medicine — a role that involves helping the school turn new discoveries into products.

The more McDonald learned about the technology, the more excited he became. Other people — including investors, health care professionals and even the major insulin manufacturers — are starting to take notice, too, McDonald said.

"It really has the potential to be a life-changing breakthrough for diabetes,"

said McDonald, who noted that his firm occasionally invests in startups.

McDonald noted that Diasome has engaged in “a dialogue” with the insulin manufacturers, but Robert Geho wouldn’t go into any more detail. He did note that Diasome eventually could end up partnering with the manufacturers or being bought by one, if all goes well.

Regardless, Diasome doesn’t “aspire to be a full-scale manufacturing company,” he said, noting that it has six employees and makes its additive through contractors.

Blair Geho started working on the technology in the 1970s, as a researcher at Procter & Gamble. During the 1980s, he continued to work on it in the background through his own company, Technology Unlimited in Wooster, which made additives for hair and skin products.

He started getting more serious about the diabetes technology in the mid-1990s, when he formed a research and development company called SDG. The Cleveland Clinic owns a stake in SDG, which owns a stake in Diasome.

“We really have put a lifetime of work into this. And a lot of money,” Blair Geho said.