

## Protein Sciences chosen

*By Mary Ellen Godin, Record-Journal business editor*

MERIDEN — Protein Sciences Corp. was selected by a Swedish vaccine maker to manufacture its therapeutic diabetes vaccine during phase III clinical trials and prepare for licensure of the drug in the United States.

The new therapeutic vaccine developed by Diamyd Medical, of Stockholm, is designed to treat type 1 and type 2 patients through protein therapy. The vaccine, named Diamyd, aims to reduce the need of insulin injections and prevent the destruction of beta cells.

The vaccine could have far-reaching effects for thousands of diabetics and puts the vaccine in the U.S. market. According to recent numbers from the Centers for Disease Control, nearly 21 million, or 7 percent of Americans, have diabetes.

“This is great news for Protein Sciences,” said Paul Pescatello, president of Connecticut United for Research Excellence or CURE. “It shows that its underlying research is cutting edge.”

Type 1 diabetes occurs when the body can't produce insulin and generally appears before age 18. It is considered an auto-immune disease, because the immune system attacks the insulin producing cells in the pancreas and destroys them. An individual with type 1 diabetes requires insulin by injection or through a pump every day.

Type 2 diabetes is more common and affects 90 percent of people with diabetes. In this type, the body can produce insulin, but it either doesn't produce enough or doesn't use it properly. Someone with type 2 uses exercise, healthy meal planning and in some cases, oral medications or insulin to control blood sugar levels. Type 2 diabetes has been linked with obesity.

The vaccine could provide months of treatment, thus eliminating the need for daily injections, Adams said.

Diamyd is now being studied in two clinical trials, one involving 70 children and adolescents and another with 160 adult type 2 patients. Protein Sciences will help prepare for an Investigational New Drug Application with the U.S. Federal Food and Drug Administration and begin phase three clinical trials in 2007.

“We are extremely happy with this strategy to continue to strengthen the company's presence in the states and at the same time accelerate the development of our diabetes vaccine,” said Anders Essen-Moller, president and chief executive officer of Diamyd Medical.

Diamyd Medical developed the vaccine using a protein system based on insect cells, the same system used by Protein Sciences for its own vaccines. The shared technology made the partnership a logical match.

“We are very intrigued by the prospects for their therapeutic Diamyd vaccine for diabetes and look forward to helping Diamyd get its product to market as quickly as possible by combining our technologies and expertise,” said Protein Sciences Chief Executive Officer Daniel Adams.

He added that the relationship with Diamyd is part of the future direction of Protein Sciences. The company hopes to get more involved in customer products they believe are likely to be successful.

Diamyd Medical also announced Monday that it is investing \$3 million in the Research Parkway vaccine maker in a separate loan investment that could convert to shares should Protein Sciences receive significant new investments.

After struggling to find capital to build its own manufacturing facility, Protein Sciences is in talks with two U.S. and one overseas potential partners to manufacture its own insect-based vaccines. Protein Sciences' influenza vaccine FluBLOK was recently approved by the FDA on a revolving license, and its Avian bird flu vaccine is also ready to be manufactured, Adams said.

According to Pescatello, finding investment capital for vaccines is risky business because the market volume can't be firmly established.

There are many small biotech companies which are making advances in treatments and cures, but need manufacturing space, he said. Protein Sciences is at the fore of the technology, but investors want to know how large the market is.

To illustrate the challenge, a company may manufacture 20 million doses of influenza vaccine but is later told that only 20,000 are needed. As a result, the company — or investors — are left paying for unused vaccine.

“Someone has to get paid for building the factory that produces the vaccine. It's something we haven't quite come to terms with in this country,” Pescatello said. “This shows that things can be done with modern vaccine research. It would be a good thing if we could put a floor under that market with the flu vaccine.”

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