

Breaking News on Pharmaceutical Technology

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Technology for long-acting proteins here to stay

By Katrina Megget

20/06/2007- **Modigene has made inroads into its development of long-acting proteins through the use of its Carboxyl Terminal Peptide (CTP) technology.**

The Virginia-based biopharmaceutical company announced positive results for its long-lasting pre-clinical formulations of human growth hormone, interferon beta and erythropoietin, which aim to be, at most, once per week injections.

This would be a stark therapeutic contrast to the three-plus a week injections required with the currently marketed drugs.

Over the past few years there has been a real drive by biopharm companies to extend the life span of therapeutic proteins, with two main techniques evolving. One is to increase the size of the therapeutic protein; the other is to alter the physical structure.

However, there are downfalls with these techniques and as a result only three long-lasting therapeutic proteins are on the market: Pegasys (PEGinterferon alfa-2A) from Schering-Plough and Roche for the treatment of hepatitis C; Aranesp (Darbepoetin alfa) from Amgen for the treatment of anemia; and Neulasta (PEGfilgrastim) from Amgen a colony stimulating factor.

Collectively, these treatments have a revenue of more than \$8bn a year.

Modigene's technology however, takes a mother nature approach to finding a long-lasting solution.

Discovered by researchers at Washington University in St. Louis, Missouri, CTP technology involves using CTP, a small peptide naturally occurring in the body as a portion of the protein human Chorionic Gonadotropin (hCG), a female hormone that helps maintain pregnancy.

By attaching CTP to other proteins it can extend the life span of the protein. Meanwhile, as both females and males, during the nine-month pregnancy period, are exposed to the protein, there is less likelihood of having an immune response to it.

Currently, Dutch biotech company Organon has attached CTP to a follicle-stimulating hormone (FSH), which is a hormone prescribed to females undergoing fertility treatments, and is in Phase III clinical trials with the product. So far, results suggest only one injection is required with FSH-CTP compared to the seven daily injections required with regular FSH.

"We are very excited about Modigene's pre-clinical work to date," Modigene's largest shareholder and board member and Teva Pharmaceutical Industries vice chairman Dr Phillip Frost said in a statement.

"With four CTP-modified proteins demonstrating to date exceptional results, including Schering-Plough/Organon's FSH-CTP now in Phase III clinical trial, and Modigene's human growth hormone, interferon beta and EPO [erythropoietin] in pre-clinical models, the CTP platform is gaining credibility as having the potential to become the platform of choice for developing long-acting therapeutic proteins."

The advantages with the technology show CTP can be attached to a variety of proteins without increasing toxicity or loss of biological activity.

According to Modigene's website, CTP-modified proteins can be manufactured using established recombinant DNA techniques in widely used mammalian protein expression systems.

"The accomplishment of this milestone was important for Modigene," the company's president Shai Novik said in a statement.

"We are moving forward with our preparations for GMP production of our lead protein candidates and initiation of clinical trials thereafter. We have also commenced development of a long-acting version of GLP-1, a therapeutic peptide that is prescribed for diabetes type II patients, and is

currently injected twice daily, and will continue to apply the technology to several other key blockbuster therapeutic proteins," he said.

The three proteins Modigene are developing reflect a big-bucks segment in the pharmaceutical industry. The human growth hormone market is worth about \$2.2bn; interferon, prescribed for the treatment of multiple sclerosis, is worth \$3.8bn; and Amgen's Aranesp reported sales of \$4.1bn last year, out of estimated EPO market of \$11.7bn.

Just yesterday, Merck-Serono announced it would be collaborating with US firm Ambrx on the development and commercialization of new product ARX201, a long-acting growth hormone product, using Ambrx's protein engineering platform ReCODE. The technology enhances hGH performance by allowing precise positioning of the site of a polyethylene glycol (PEG) polymer through biosynthetically incorporating a chemically unique amino acid.

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