

**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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