

## Breaking News on Pharmaceutical Technology

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# CTP is "best-of-breed" for enhancing protein longevity

By Gareth Macdonald

16/07/2008- **Modigene says that data from a trial of a Schering-Plough's (SP) fertility stimulation hormone (FSH-CTP) confirms that carboxyl terminal peptide (CTP) modification can extend the therapeutic duration of protein drugs.**

Techniques to boost the half-life of therapeutic proteins fall into two main categories with developers choosing to either increase the size of the drug molecule or alter its physical structure in an effort to extend its durability in circulation.

Such approaches are fraught with technical difficulties and, to date, only a handful of extended-release drugs have been commercialized. Despite this, products that have been launched, such as SP's Pegintron (peginterferon alfa-2B), Amgen's Aranesp (Darbepoetin alfa) and Neulasta (PEGfilgrastim), generate revenues of around \$8bn a year.

The CTP approach, which was developed by researchers working at Washington University in St. Louis, Missouri, attaches a small portion of the female pregnancy maintenance hormone chorionic gonadotropin (hCG) to the molecule under development, markedly improving its circulatory half-life.

Shai Novik, Modigene's president, told in-PharmaTechnologist.com that: *"The CTP peptide is basically a best-of-breed technology to enhance protein longevity. PEGylation, DNA mutations and Albumin fusion are the technologies that have mainly been used to date, and CTP has the positive properties encapsulated in each, but is a natural peptide we all carry in our bodies and therefore non-immunogenic."*

*"The three main important properties of a technology to extend protein longevity are: Create a durable protein; that maintains comparable biological activity; and is non-immunogenic. The CTP offers all three in a small peptide that can be attached once or multiple times to a protein of choice to extend durability. Unlike technologies like PEGylation and DNA mutation, which involve trial-and-error to find the right combination that may work, the CTP technology is a simple attachment of the CTP peptide to the authentic molecule,"* Novik explained.

He added that because: *"the CTP platform is applicable to all therapeutic proteins and peptides. The market for the proteins we are currently going after is \$2.2bn for human growth hormone, and \$4.3bn for interferon beta. There are many other therapeutic proteins representing over \$50bn in annual sales."*

### Clinical trials due next year

SP's Phase III trial, known as ENGAGE, compared the effectiveness of a single FSH-CTP in 1,509 women suffering from a variety of fertility problems. The results showed that pregnancy rates in subjects who received the single injection were comparable with those who received seven consecutive FSH injections.

Modigene is applying the CTP technology to its human growth hormone (hGH) and interferon beta (IFN-beta) programmes. Specifically, the firm is seeking to establish products that require only once-a-week administration, in contrast with the three to seven times a week injections demanded by currently available competitor treatments.

Company CEO, Avri Havron, said that the: *"The success of Schering-Plough's Phase III trial of its long-acting FSH fertility hormone marks a major milestone for the CTP platform technology that is the basis for our new drug pipeline."*

*"We believe these positive results provide independent support of our own plans for clinical trials of Modigene's CTP-enhanced versions of human growth hormone and interferon beta that we intend to*

*initiate next year,"* he added.

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