

### **Cape Biotech backs CSIR technology to produce an affordable HIV antiretroviral peptide**

#### **Strain of bacteria genetically engineered to express sought-after antiretroviral peptide**

It's one of the most effective antiretroviral treatments for HIV, but hopelessly unaffordable for most patients in sub-Saharan Africa. Now scientists at the CSIR have developed a bio-manufacturing process for Enfuvirtide that may just change all of this. And Cape Biotech, the Department of Science and Technology-funded biotechnology innovation centre, believes the scientists are onto something, announcing that it is funding proof of concept studies.

Dr Maureen Louw, a CSIR molecular biologist with many years' experience in genetic engineering of bacteria, is heading up the project. "Instead of using a chemical process - which is how this therapeutic is currently commercially made - we have genetically modified a microorganism so as to harness the organism's natural ability for protein secretion and to channel it into over-expressing the peptide we need.



Dr Maureen Louw

"Since these therapeutic peptides would be needed in large quantities, we will use fermentation processes to multiply the recombinant bacteria, and therefore increase the yield of peptides obtained. The aim is to achieve this in a more cost effective manner than the chemical process behind the commercial product on the market, which reportedly uses 106 chemical steps and 44 ingredients and is cited as the reason for the record-breaking price of the commercial product."

The CSIR has developed the technology and is now at the stage that the organisation will further refine and evaluate the cost competitiveness of the technology.

Dr Louw and the team are excited by the progress in a domain with such relevance to South Africa's people. "To put a highly effective antiretroviral treatment within the reach of our HIV-positive population would be a career highlight for all of the scientists on the project. Every scientist wants his/her work to move from the laboratory into a real life application. This investment by Cape Biotech brings us one step closer to this ideal," she says.

The scale of HIV in South Africa means that the country makes up a major portion of the global antiretroviral market. Estimates are that, if all those South Africans requiring antiretroviral treatment, receive it, South Africa would represent nearly 40% of the global market. In this context, the benefit of a cheaper, locally manufactured drug speaks for itself.

Enfuvirtide is a peptide that blocks HIV infection by preventing the virus from entering the yet uninfected cells. It has become the preferred agent for heavily treatment-experienced patients who require a therapy change to improve immunologic status.

"Clinical data have confirmed Enfuvirtide's role in decreasing viral loads. But the estimated R19 300 treatment cost per patient, per month, is likely to forever prevent its pervasive use," comments CSIR research and development outcomes manager, Fanie Marais.

Cape Biotech project manager, Fred van der Post, says they are excited by the potential this project holds for the local manufacturing of antiretrovirals, and the development of a local active pharmaceutical industry. It is envisaged that successful proof of concept will lead to the technology being licensed either to an existing South African enterprise, or to a new public, private partnership.

Over the next two years, a team of CSIR molecular biologists, together with fermentation technologists from the University of Cape Town Chemical Engineering Department and the Technical University of Berlin will be working together on increasing expression levels through genetic improvements; proof of concept studies for the production of successful products in batch fermentation; and the scale up of the experiments to pilot scale levels.

The CSIR's work is protected by international patents relating to the recombinant bacterial strain and a number of industrial applications associated with its use.

- Alida Britz

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Tel: + 27 12 841 2911, technical enquiries: + 27 12 841 2000, fax: +27 12 349 1153, web site feedback:

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