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CureVac enters premier biotech league with new cancer vaccine

At present, active immunotherapy seems to produce the best results in the treatment of cancer. The Tübingen-based biotech company CureVac is now hoping to achieve a breakthrough in cancer therapy with a worldwide unique vaccine. The first clinical trials have recently commenced.

It has long been known that there is a close relationship between the body's immune defence system and the development of cancer. Patients who have received a transplant and who are treated with immunosuppressive drugs to prevent the rejection of the transplanted organ, are three or four times more at risk of developing a tumour. Some of the latest cancer treatment strategies focus on mobilising the immune system of such patients to enable it to specifically attack tumour metastases, and potentially also the tumour itself.

In the development of highly specific cancer vaccines, many researchers exploit the fact that the majority of cancer cells have characteristic protein structures on their surface that act as potent antigens. The researchers use genetically modified tumour cells as well as DNA-containing plasmids and a range of tumour-associated peptides. However, none of these substances has achieved the desired breakthrough in therapy. A new, highly promising approach has been developed by the Tübingen-based biotech company CureVac whose vaccine is based on modified messenger ribonucleic acid (mRNA) which codes for tumour-specific antigens. The vaccine is now being tested on patients suffering from prostate carcinoma.

"The modified mRNA, which is injected into the skin, leads to the formation of protein antigens which induce an immunological reaction to the tumour cells," said Dr. med. Thomas Lander, Managing Director and Chief Medical Officer of CureVac, explaining the mRNA's mechanism of action. Curevac used its proprietary RNActive® technology to design the modified mRNAs.

The recently commenced phase 1 clinical trial will mainly focus on assessing the tolerability and safety of the vaccine. Lander is confident: "In contrast to DNA-based vaccines, mRNA is not integrated into the patients' genome and there is no uncontrolled recombination with the genome." Since the immune response is ideally only directed at cancer cells and not healthy cells, the new treatment will not lead to the severe side effects usually experienced when undergoing chemo- or radiotherapy.

In addition, the mechanism of action of Curevac's new vaccine has other major advantages. "For example, vaccines based on tumour-associated peptides only use small sequence segments of the

Dr. med. Thomas Lander, Managing Director and Chief Medical Officer of CureVac

tumour antigen. Our approach however enables the complete expression of the corresponding protein," explained Lander. This guarantees that all chemical structures of an antigen that are needed for an effective immune response to occur are actually available in the organism.

Globally unique production method

Up until recently, mRNA molecules were regarded as far too instable to be used therapeutically. The method developed by CureVac now enables the modification of mRNA so as to prevent it from being degraded in the cell. "We only use constituents that are natural constituents of mRNA," reported Lander. The mRNA is eventually complexed with positively charged peptides, which also contributes to its stability.

"During the company's start-up phase we very much concentrated on the production of these novel molecules," reports Lander adding "this is very untypical for small start-up biotechs". However, the risk paid off. "With our patented PUREmessenger® technology, we are the only company in the world that are able to produce RNA according to GMP standards," said the medical expert who worked for many years in big pharmaceutical companies before becoming part of the CureVac management team.

CureVac's new cancer vaccine is based on modified mRNA molecules

Active immunotherapy requires time and patience

CureVac has chosen prostate carcinomas as the first therapeutic area for its new vaccine. This decision was based on the fact that four different tumour antigens are known and present in almost all prostate cancer patients. In addition, prostate carcinomas grow very slowly, which is greatly advantageous when using active immunotherapy to treat the tumour. It often takes up to 12 months before a cancer vaccine has exerted its full effect. "Unfortunately, this type of therapy is not very suited to the treatment of aggressive tumours such as pancreas carcinomas," said Lander.

Lander is extremely optimistic that CureVac's CV9103 vaccine will be successful in the treatment of prostate carcinoma. "The preclinical animal experiments were very promising." We found that CV9103 led to a strong immune response in mice and to a considerable slowing down of tumour growth. This was the basis for CureVac's application for the clinical testing of CV9103 in Germany and the USA, and the company has received approval in both cases. "We received the go-ahead from the German authorities in December 2008, and we also now have authorisation from the American authorities," said Lander delighted with the success.

CureVac's developments have become possible thanks to the help of investors, with Dietmar Hopp as one of the largest. The co-founder of the SAP software group of companies has so far invested 35 million euros in the Tübingen-based biotech. And who knows, Hopp may soon hit the headlines for reasons other than his role as the sponsor of the successful German football team "TSG 1899 Hoffenheim".

Further information:
CureVac GmbH
Paul-Ehrlich-Str. 15
72076 Tübingen
Tel.: +49 (0)7071 92 0 53-0
Fax: +49 (0)7071 92 0 53-11
E-mail: communications(at)curevac.com

Article

02-Feb-2009
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The article is part of the following dossiers

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