

Media Release

For immediate publication

Pevion Biotech takes first vaccine into clinical development

Beginning of a phase I testing period for an innovative malaria vaccine – close co-operation with the Swiss Tropical Institute in Basel – first results expected by end of 2004

Bern, October 30th, 2003 – Pevion Biotech has announced the start of phase I clinical development of their first vaccine. In close co-operation with the Swiss Tropical Institute in Basel, the synthetic peptide vaccine for the prevention of malaria is being administered to 46 volunteers at the cantonal hospital in Basel in order to test its tolerability and immunogenicity.

Peter Klein, CEO of Pevion Biotech, comments: “We are very pleased to be able to take our first vaccine into clinical testing less than two years after of the founding of our company. We have made an important step in developing a new generation of vaccines on the basis of our unique technology platform which trigger specific immune reactions in the human body, show fewer undesirable side effects and meet the highest possible safety standards.”

Professor Gerd Pluschke, Head of the Molecular Immunology Department of the Swiss Tropical Institute (STI), explains: “The struggle against malaria is a big challenge due to the lack of an existing vaccine against this disease. Since all the potential vaccines against malaria which have been tested so far have shown a limited protective efficacy at best, we have developed a new technology – the anchoring of synthetic peptide mimotopes on the surface of virosomes. The thus created synthetic vaccine promises focussed effects without undesirable side effects. The collaboration with Pevion offers a great chance to provide effective protection from malaria to all people at risk, especially to children in third-world countries.”

The STI, committed to the development of malaria vaccines and possessing an extensive infrastructure including their own testing centre in Africa, is a partner of Pevion not only for basic research, but also for the clinical study of the new vaccine. The study will be completed within about one year and, positive results permitting, it is Pevion’s aim to take the product quickly to phase II and to find a suitable partner for further clinical development and possible marketing.

About the clinical trial

The phase I clinical trial is being carried out on 46 healthy adult volunteers as a randomised, placebo-controlled blind study. The primary aim of the study is to examine the safety and tolerability of two formulations of the synthetic vaccine, alone and in combination. Secondary objectives include assessments of the vaccine’s immunogenicity. It must be stressed that there is no intention of conducting an experimental infection of the study subjects in order to examine the protective effects (a so-called malaria-challenge) in any of the trial groups. In the course of the study, each subject will receive two to three vaccinations and will then be closely monitored. The study is scheduled for completion by the end of 2004.

The technology platforms of Pevion Biotech

Pevion Biotech is using two unique virosome technology based technology platforms. The two platforms PeviPRO™ and PeviTER™ utilise virosomes: spherical lipid vesicles in which fusion

proteins of the influenza virus are incorporated. These virosomes maintain the natural fusion activity which is characteristic for viruses and thus are immunogenic without being infectious. By coupling or incorporating peptide epitopes of the pathogens with virosomes, it is possible to make the human immune system aware of these pathogens and enable it to prepare an appropriate immune response. Depending on where the peptide epitopes are located, either a humoral (PeviPRO™) and/or cellular (PeviTER™) immune response can be created, thus allowing either a prophylactic or therapeutic use of the vaccine.

The malaria vaccine PEV3A, based on PeviPRO™ technology, presents to the immune system three-dimensionally defined peptide epitopes, developed in co-operation with the university of Zurich, which mimic the natural surface structures of the malaria parasite *Plasmodium falciparum*.

Two Berna Biotech vaccines based on virosome technology have already been registered by the authorities in over 29 countries and administered to more than 10 million people.

About Malaria

Forty percent of the world population live in areas affected by malaria, and more than one million people per year – mostly children – die from this disease. The parasite is developing increasing resistance to common prophylactic and therapeutic medicines and its carrier, the Anopheles mosquito, is resistant to most insecticides. As yet, there is currently no effective vaccine available against malaria.

Pevion Biotech is specialised in the development of vaccines, based on the proprietary virosome technology platforms, from the research phase to the start of clinical trials. With its know-how in screening and development and the technologies of the founding companies in the field of peptide chemistry and virosomes, Pevion Biotech is a partner for research institutes as well as for members of the pharmaceutical industry with a particular interest in the accelerated development of prophylactic or therapeutic vaccines. Pevion Biotech was founded in 2002 as a joint venture of the vaccine enterprise Berna Biotech AG (Berne) and Bachem AG (Bubendorf), the world-wide leading independent producer of peptides.

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