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Preclinical trial success with new influenza vaccines

Novel virus-like particle (VLP) vaccines against several influenza virus strains have been developed by Novavax Inc. (PA, USA) with positive results from preclinical studies. The company is now planning human clinical trials.

VLPs are similar to real viruses, but lack the genetic material required for viral replication. They are also capable of triggering immune responses against the viruses that they resemble.

"The use of VLPs as vaccines for humans is relatively new, and these vaccines have distinct advantages over other types of vaccine strategies," said Ted Ross of the University of Pittsburgh (PA, USA), a collaborator of Novavax. He added that they can "provide a more robust and broadly protective immune response at lower dose".

Seasonal influenza vaccines are given currently as one dose to adults, but two doses are necessary in young children. Furthermore, other human clinical trials have suggested that at least two doses are needed for pandemic influenza vaccines.

A single dose of Novavax's VLPs induces protective antibody levels against influenza in several preclinical animal models. Data also indicate that a lower dose may be sufficient to produce protection. This is highly desirable in the pandemic situation and would allow increased immunization coverage.

"These results are highly encouraging and are an early affirmation of the strength of our VLP platform," said Rick Bright, Novavax's Vice President of Vaccine Development.

Novavax is working with regulatory authorities to plan human clinical trials in the USA and India. "We are eager to see how well this (preclinical trial result) translates into humans," added Bright.

Plague vaccine moves into Phase II clinical trial

DynPort Vaccine Company (DVC), (MD, USA) has recruited 400 healthy volunteers for a Phase IIa clinical trial of its candidate plague vaccine rF1V. The trial will be carried out at eight locations across the USA and results are expected towards the end of next year. It aims to establish safety and immunogenicity of rF1V with different dosages and regimens.

"An effective, licensed plague vaccine is a crucial component of US biodefense initiatives," said Robert House, president and chief scientific officer of DVC. "Plague has been identified as a Category A bioterrorism agent by the Centers for Disease Control and Prevention."

rF1V originates from the US Army Medical Research Institute of Infectious Diseases (USAMRIID). Scientists have identified antigens that may induce protection against the plague bacterium *Yersinia pestis* and have also developed assays to assess the performance of vaccine candidates. USAMRIID's role in the US national defense is to carry out basic research on infectious disease. rF1V has been passed on to DVC for further development, production and clinical trials.

The candidate vaccine has not been licensed by the US FDA because its safety and efficacy have not been established. DVC has launched a Phase IIa clinical trial with rF1V while trying to complete a Phase I trial, which started in 2004, in order to meet its milestones.

Stimuvax® can delay prostate cancer development

After the success in prolonging the survival time of patients with lung cancer in April this year, Biomira Inc. (Canada) has claimed that its cancer vaccine, Stimuvax®, could also delay the development of prostate cancer. This pilot study was published in the July issue of the *Journal of Urology*.

Designed to help the immune system target cancer cells, Stimuvax contains a 25-amino acid fragment of the cancer protein, mucin 1, wrapped in liposomal vesicles. Liposome can enhance the delivery and recognition of antigens in vaccines.

A total of 16 patients with postsurgical prostate cancer were enrolled in a new Phase IIa study. The patients were treated with one dose per week for 8 weeks, followed by one dose every 6 weeks. The treatment lasted for approximately 1 year with 15 doses of Stimuvax per patient.

The prostate-specific antigen (PSA) is an indicator for prostate cancer progression, with higher levels of PSA corresponding to increased severity of the disease. Out of 16 patients, Stimuvax stabilized PSA levels in eight patients and extended PAS doubling time in six patients. This result warrants further clinical trials in this type of population.

Postsurgical prostate cancer patients have few choices other than androgen-deprivation therapy (ADT). "Delaying the time to PSA level doubling may defer initiation of this treatment and spare patients the negative impact of the only therapy available to them for a longer period of time," said Scott North, the research team leader. "Since men with a longer PSA doubling time can expect longer survival than those with shorter times, a strategy to lengthen the time to doubling may favorably impact the disease," he added.

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