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Trial Watch

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Trial Watch

Human papillomavirus vaccines

Merck's anti-human papillomavirus (HPV) vaccine, Gardasil™, has proven effective at preventing genital warts, vaginal dysplasia and vulvular dysplasia caused by infection with four different strains of HPV, all of which are known to be associated with cervical cancer.

Of these strains, HPV types 16 and 18 are together responsible for approximately 70% of all cases of cervical cancer, while types 6 and 11 are associated with approximately 90% of genital warts and 25% of low-grade lesions.

The results of efficacy trials were presented at the 45th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) (16–19 December, 2005, Washington DC, USA). Approximately 5000 sexually active women aged 16–24, who were free from HPV infection at the time of enrollment on the study, received three vaccinations of either Gardasil or placebo at the start of study and again at 1 and 6 months. Patients were assessed by complete genital examinations, as well as six Pap smears and five blood samples.

Among the women who received three doses of Gardasil, there were no cases of genital warts or high-grade vaginal or vulvular dysplasia, compared with 40 cases (1.8%) of warts or precancerous lesions in the placebo group. The vaccine was well tolerated, with the worst side effects observed being injection-site redness and/or swelling. Based on its safety and 100% efficacy, Merck has submitted the vaccine for FDA approval.

In another presentation at the ICAAC, GlaxoSmithKline (GSK) reported results from a Phase III trial of its candidate HPV vaccine, Cervarix™, which targets HPV types 16 and 18. This trial was conducted in 158 girls aged 10–14 and 458 women aged 15–25, who received three doses of the vaccine over a 6-month period. Among both age groups, all participants experienced seroconversion. Interestingly, geometric mean antibody titers were significantly higher in the 10–14-year-old group compared with the 15–25-year-olds (17,273 vs 7293 for HPV type 16 and 6864 vs 3319 for type 18). Based on their data, investigators at GSK suggest that Cevarix may provide strongest protection if given to girls before they are sexually active. However, antibody titers among the older age group were also high enough to elicit protection from HPV infection.

"Both of these vaccines have proven incredibly effective in preventing the early forms of the dysplasias that lead to cancer," said John Schiller (National Cancer Institute, Bethesda, MD, USA). "These are very exciting developments."

Follow-up data from Phase II BiovaxID™ trial and ongoing Phase III update

Biovax International, Inc., a subsidiary of Accentia Biopharmaceuticals, Inc., has reported long-term follow-up data from its Phase II clinical trial of BiovaxID™, a personalized vaccine for follicular non-Hodgkin's lymphoma (NHL).

Patients with NHL originally treated with BiovaxID in the Phase II trial have now been followed for a median of 9.2 years. Of these patients, nine (45%) remained in clinical remission at their most recent follow-up; median disease-free survival was 96.5 months (8.04 years) and the overall survival rate was 95%.

Steve Arikian, CEO of Biovest International, said, "The length of the follow-up time and impressive remission data from our Phase II trial gives us confidence in the utility of BiovaxID for the treatment of follicular lymphoma. Having accelerated enrollment in our ongoing Phase III trial, we are now planning a commercial facility to enable us to deliver BiovaxID to those who need it if BiovaxID is approved."

To date, 187 patients have been enrolled in the study and treated with BiovaxID immunotherapy following PACE (prednisone, doxorubicin, cyclophosphamide and etoposide [ProMACE without methotrexate]) chemotherapy. Of these patients, 145 (77.5%) achieved a clinical or unconfirmed complete remission and are being followed in the ongoing Phase III trial.

Barry Gause, coinvestigator for the clinical trial at the National Cancer Institute, commented, "The results of this Phase II study compare very favorably with chemotherapy alone and with cyclophosphamide, hydroxydaunomycin, oncovin and prednisone (CHOP-PR), where the median disease-free survival is 2.2 years and 6.9 years, respectively. The ongoing Phase III trial of BiovaxID versus nonspecific immune stimulation should help to clarify the role of vaccine therapy in patients with follicular lymphoma."

"We are encouraged by these long-term follow-up data from our Phase II study," said Angelos Stergiou, Director of Product Development at Accentia. "These results underscore the potential of BiovaxID as a promising personalized therapeutic vaccine for follicular lymphoma. Patients, physicians and payors are understandably requesting that, at some point in the battle against cancer, expensive cancer therapeutics need to start to provide cures. Because this disease is considered incurable with existing therapies we are particularly pleased with the reported rate of overall survival without tumor recurrence, which is the gold standard for cancer therapeutics."

BiovaxID provides a targeted, customized therapy by using high-fidelity copies of each patient's tumor-derived Id protein (tumor antigen), which is conjugated to keyhole limpet hemocyanin and administered with granulocyte–macrophage colony-stimulating factor. The vaccine is an active immunotherapeutic that primes the immune system to induce a cell-mediated immune response to cancerous lymphoma cells but not to normal B cells.

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