
Cancer Vaccine Developer Advaxis Taps Numoda For Funds, Clinical Tech

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Publicly traded Advaxis Inc., whose vaccines are designed to train the immune system to destroy tumors, has raised an undisclosed sum from Numoda Corp. to advance a product that may extend the lives of women with cervical cancer.

Numoda, an information- and process-management company that helps drug companies manage clinical trials, provided the financing through its investment arm, Numoda Capital Innovations. Numoda Corp. is running Advaxis's clinical program and is using its technology to accelerate the company's data-processing capabilities, said Chief Executive Thomas A. Moore.

Wednesday evening Advaxis said it had seen positive preliminary results of a Phase II study of 87 cervical-cancer patients whose tumors had resumed growth, and in most cases spread, despite radiation and/or chemotherapy. As of Jan. 25, 62% of patients receiving its ADXS-HPV vaccine were alive at six months post treatment, 41% were alive at nine months, and 40% were alive at the one-year mark.

By comparison, earlier Phase II studies of similar patients treated with cisplatin and pentoxifylline had a median overall survival rate of 6.2 months and a one-year survival rate of about 5%, according to Advaxis.

Three patients in the Advaxis study had their tumors eliminated completely and four saw a greater than 30% reduction in their tumor burden, Advaxis said. The company, which expects to enroll a total 110 patients, is conducting the study in India. Some of the participants also received the chemotherapy cisplatin, while others did not. Final results are expected in about a year, according to Advaxis. If positive, the vaccine would move into Phase III clinical trials.

Advaxis is one of several companies trying to make therapeutic vaccines into mainstay treatments for cancer. By inducing an immune-system attack on tumors, these vaccines have potential to treat cancer and prevent it from recurring, proponents say. The Food and Drug Administration approved the first therapeutic-cancer vaccine in April 2010: Provenge, a Dendreon Corp. treatment used in certain advanced prostate-cancer patients.

Advaxis's approach differs from Dendreon's. Unlike Provenge, Advaxis vaccines don't require that cells be harvested from the patient. Instead, Advaxis uses live, attenuated *Listeria monocytogenes* that are bioengineered to secrete an antigen/adjuvant fusion protein. This fusion protein redirects the immune response that humans have developed to *Listeria monocytogenes* toward the cancer, according to the company.

Advaxis vaccines seem to be able to direct the immune system to attack multiple tumor antigens through a process known as epitope spreading. This means tumors cannot easily avoid the immune-system attack through mutations, according to Moore.

In animals, Advaxis eliminated preexisting cancers 75% of the time. Animals successfully treated with the vaccine also became immune to the same type of cancer, Moore said. Advaxis, based in Princeton, N.J., has yet to see evidence that its vaccines will induce the immune system to attack normal tissue, according to Moore.

Cervical cancer is almost always caused by human papillomavirus. The National Cancer Institute estimates that 12,170 new cases will be diagnosed in the U.S. this year and that the disease will cause 4,220 deaths. The vaccines Gardasil and Cervarix can protect against HPV infection but can't be used to treat cervical cancer.

Advaxis's HPV vaccine is designed to target cells expressing the HPV gene E7, a gene involved in transforming certain HPV-infected cells into dysplastic or malignant tissue. The vaccine is designed to infect antigen-presenting cells to set off an immune attack on these abnormal or malignant cells. As a result, cytotoxic T cells infiltrate and attack tumors. The vaccine also appears to inhibit mechanisms that help the tumor survive, such as regulatory T cells that turn down the immune-system attack, according to the company.

The hope is that immunotherapies such as these will enable patients to keep tumors in check, just as antiviral drugs enable people to live with HIV, Moore said.

In addition to its cervical-cancer vaccine, Advaxis's pipeline includes a cervical-dysplasia vaccine now in Phase II studies in the U.S. Cervical dysplasia, or abnormal changes in the cells of the cervix, can lead to cancer if left untreated. This year Advaxis intends begin clinical studies of therapeutic vaccines for breast and prostate cancer, Moore said.

Other companies targeting this market include venture-backed Genticel SA, which is developing therapeutic HPV vaccines for adult women infected with human papillomavirus genotype 16 or 18. The vaccine is designed to treat HPV before cervical cancer develops.

Advaxis has a cash runway to last three months, Moore said. The company has raised a series of small financings as needed in an effort to minimize dilution, he said.

<http://www.advaxis.com>

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