

Advexin – A modified cold virus is used to carry the healthy genes into the body.

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*Source:* <http://sci.tech–archive.net/Archive/sci.med.diseases.cancer/2007–07/msg00075.html>

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  - *Date:* Sun, 29 Jul 2007 06:27:28 –0400
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<http://www.chron.com/disp/story.mpl/health/1729568.html>

Jan. 8, 2003, 8:11PM

## REPLACING MUTANT GENES

Drug that attacks cells in tumors is showing promise in study

By DEBORAH MANN LAKE

Special to the Chronicle

A gene therapy drug that attacks cancerous tumor cells has shown early positive results in reducing the size of breast cancer tumors in advance of surgery or radiation treatment.

The University of Texas M.D. Anderson Cancer Center is now studying the drug, Advexin, in combination with standard chemotherapy treatment.

"We've had promising results in the 12 patients enrolled in the trial so far," said Dr. Massimo Cristofanilli, assistant professor in M.D. Anderson's department of breast medical oncology and the study's principal investigator. "All have had some sort of response. One important thing is that it's safe. There are no problems with toxicity because it's not systemic."

Cancer occurs when defects in genes tell cells to divide uncontrollably until they can no longer function correctly.

"It's like removing the brakes in a car," said Dr. Jack Roth, M.D. Anderson professor and chair, thoracic and cardiovascular surgery, and director of the W.M. Keck Cancer Center for Cancer Gene Therapy. "Because cancer is a genetic disease, we try to put back in normal genes."

A modified cold virus is used to carry the healthy genes into the body.

"The virus attaches to the cell and delivers the payload," Roth said.

Advexin, injected directly into the tumor site, replaces damaged tumor-suppressing p53 genes with healthy genes which researchers believe can immediately destroy cancer cells as well as attack future ones.

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It has already shown positive results in trials with head and neck cancers.

"P53 is a very important gene that acts as a guardian and allows the cell to repair damage to the genes," Roth said. "In addition to killing breast cancer cells, it may stimulate the immune response to the cancer."

The breast cancer trial is sponsored by the drug's Houston-based developer, Introgen Therapeutics Inc.

"Cancerous tumor cells can become resistant to chemotherapy, so replacing the mutated p53 gene makes the tumor more sensitive to chemotherapy," Cristofanilli said. "P53 tells the tumor cells to stop growing."

The trial will eventually recruit 60 patients with locally advanced breast cancer, which includes a tumor between 2 and 5 centimeters and cells that have spread to the lymph nodes.

Locally advanced breast cancer accounts for up to 15 percent of newly diagnosed cases. Research has shown that it has a high frequency of damaged p53 genes, which has been associated with decreased survival rates.

"Generally at that stage, surgery alone or chemotherapy and surgery don't control the tumor very well," Roth said.

Patients receive the chemotherapy drugs Taxotere and Taxol with Advexin during four treatment cycles spaced three weeks apart.

Houstonian Maxine Johnson, diagnosed with breast cancer in June, said she didn't hesitate to join the trial after it was explained to her by Cristofanilli. Breast cancer runs in her family and she has already lost a sister to the disease.

"I'm very happy to be part of the trial. The tumor has shrunk an awful lot. I told Dr. Cristofanilli that I'm his miracle lady," Johnson said.

The most difficult part of gene therapy is applying results in the lab to the patient, Cristofanilli said. "This trial is proving the concept that gene therapy can enhance chemotherapy treatment."