

Stimuvax doomed in lung cancer



[Elizabeth Cairns](#)

The failure of Stimuvax in the phase III Start trial in non-small cell lung cancer is another bad omen for cancer vaccines. It is also a bad knock to the drug's originator, Oncothyreon, which would have received a \$90m payment from its licensee Merck KGaA had the drug been able to improve overall survival.

Merck is trying to accentuate the positive, insisting that "notable treatment effects" were seen in certain patient populations, though it declined to specify which groups exactly. The company plans further analyses in these patients, but it appears unlikely that Stimuvax has much of a future in NSCLC. Its fate now depends on its development in colorectal and prostate cancers, for which it is in phase II.

The result was not entirely unexpected given the conclusion formed by the trial's independent data safety board in March that efficacy was not good enough to halt the trial early ([Oncothyreon falls back as Stimuvax results wait another year, March 7, 2012](#)).

Another phase III study of Stimuvax, Inspire, is being conducted in China, Hong Kong, South Korea, Singapore and Taiwan, and is to continue "pending discussion with relevant regulatory agencies", Merck said. The trial's design is near-identical to that of Start, with the main difference being that it has enrolled patients of Asian heritage.

Disappointment

Cancer immunotherapies as a class are no strangers to failure. The only such product to make it to market, Dendreon's prostate cancer vaccine Provenge, is a byword for disappointment.

As for those in development, GSK's phase III-stage melanoma and NSCLC vaccine MAGE-A3 is one of the leaders, but even this is given just a 10% chance of approval by some analysts ([Event - MAGE-A3 vaccine must prove its worth, December 14, 2012](#)). Stimuvax itself had been given a 20% probability of success by UBS analysts. Elsewhere, Northwest Biotherapeutics is conducting a phase III trial of its cancer vaccine DCVax-L in glioblastoma, but the firm is running out of cash, and the trial is not due to report until summer.

The failure of Stimuvax has hit both companies hard. Merck's share price was down 3% to €98.02 this morning, but Oncothyreon's shares plummeted by 60% on the Nasdaq and stood at \$1.91 in late morning trading. The Seattle-based company's only other project is PX-866, a phosphoinositide-3 kinase (PI3K) inhibitor - another class of compounds that has disappointed, most recently with the loss of Keryx's perifosine ([Perifosine failure has Keryx pivoting away from cancer drugs, April 3, 2012](#)).

But whatever the prospects for Oncothyreon as a company and cancer vaccines as a class, Stimuvax is finished in NSCLC. Andrew Whitney, an analyst at UBS, said that the chances of the drug gaining eventual approval were less than 5%, and even then only after two or three years and several further trials. Cancer vaccines look more and more like a forlorn hope.

Study name	Trial ID
Start	NCT00409188
Inspire	NCT01015443

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow [@LizEPVantage](#) on Twitter

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Evaluate HQ
[44-\(0\)20-7377-0800](tel:44-(0)20-7377-0800)

Evaluate Americas
[+1-617-573-9450](tel:+16175739450)

Evaluate APAC
[+81-\(0\)80-1164-4754](tel:+8108011644754)

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