World's first cancer vaccine enters unusual market

Dingy Doorway

The first immunotherapy for cancer has been approved, but health experts aren't rejoicing. Why? Take a look at the vaccine's exotic history.

Recently, Antigenics, a small biotech company from New York, announced that their cancer vaccine, Oncophage, had been approved. Immediately a startled murmur rippled through the community of experts, particularly when the exotic location of the vaccine's approval was revealed. Why?

Oncophage has a long history. The drug is a therapeutic vaccine to target specific types of kidney cancer cells. Proteins extracted from patient's tumour tissue that (according to Antigenics) activate the immune system are enriched *in vitro* and then returned to the patient by injection through the skin. However, the drug didn't gain the acceptance of the US licensing authorities on their first attempt in March 2006. After twelve years of development and $425 million spent, the poor results of a final phase III trial in more than 600 patients didn't satisfy FDA (U.S. Food and Drug Administration) officials, suggesting that the vaccine cannot delay the recurrence of kidney cancer. The vaccine's claimed benefits were little more than a fluke (or, speaking more provocatively, possibly fake).

Photo: MarkSpitzUSA.com

Olympic swimming hero Mark Spitz, whose father has suffered from kidney cancer, campaigned with Antigenics in 2004 to promote kidney cancer awareness.

Russian regulation rather less rigorous

That's why Antigenics' CEO, Garo Armen, decided to step off the beaten track. He found new opportunities in Russia, where healthcare regulations are much less demanding than in western countries such as the USA and in the EU. Antigenics provided the Russian authorities with a self-selected subset of its previously insufficient 2006 data. In April this year their time came: The Russian Ministry of Public Health took its foot off the brake and approved the world's first cancer vaccine, permitting the sale of a medical product that failed a late-stage clinical trial in the USA. According to Armen, Oncophage will be commercially available in Russia by mid 2008 (initially in ten hospitals located in Moscow and St. Petersburg).

That was good news for Antigenics' shareholders. Stock rose more than 20 percent to $3.03 once the news broke (but is still light-years away from its all time high of $50.25 in March 2000). The news is also good for Antigenics, of course. The Russian pharmaceuticals market is growing strongly, implying that increasing numbers of patients are able to pay for the expensive treatment (Armen referred to as much as $60,000 per patient per year). A quarter of Russia's annual 16,000 new cases of kidney cancer could benefit from Oncophage, says Armen. This market is worth $240 million.

Investors smell a rat. A $21 million private investment in Antigenics was clinched shortly after the Russians' approval.

Future bleak in Western countries

The FDA does not consider retrospective subset analysis to be a suitable measure of success, arguing that results can be biased. Therefore there is little hope that Oncophage will be approved in the United States without further (and expensive) trials. It remains to be seen how the European Medicines Agency (EMEA) will approach this topic. Antigenics plans to file for approval in Europe by the end of the year, but definitely won't conduct additional trials. "No one in their right mind would authorise that," said Garo Armen, the company's CEO, in an interview, "[not] even if we had the money."

In any case, the whole affair stinks to high heaven. The question is whether other small biotech companies will follow Antigenics' lead and seek to market their products in developing countries. Could a whole new market be opening up to facilitate offloading dodgy drugs? W. Koeppelle

Clinical trials in the 3rd world

Taking the Easy Way

A German firm raises mistrust, when performing its clinical studies in India.

Modesty isn't a behaviour that characterises Mark Freyberg, Chief Executive of Cytotools. When promoting the prospects of his small biotech holding, located in Darmstadt, Germany, Freyberg juggles with billions. Wound healing? – Awesome! Bargain for a market volume of $3.4 billion. Chronic urinary tract infections? – Er, should yield $9.0 billion. Arteriosclerosis and other cardiovascular diseases? – Well, there are additional $58 billion to take away!

Freyberg's company with its five employees currently has an insignificant market capitalisation of €4.5 million but he wants to turn it into "one of the most successful technology holdings". It's a secret how he wants to realise this goal. Cytotools' executives reject journalists' efforts to contact them, saying they don't want to be interviewed.

However, there are so many questions to answer. Why did the stock lose more than 70 percent in the last 24 months? Why does the Cytotools homepage provide so little information? And why, for the world, does the company perform its clinical studies not in Europe but in India? -wk-