

December 2008

Founded

1998

Focus

Cancer vaccines

Employees

25

Investors

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Company Profile

Onyvax Ltd is a biotechnology company developing therapeutic cancer vaccines that harness the selective power of the immune system to seek and destroy tumor cells. Founded in 1998, Onyvax has taken its lead product for the treatment of prostate cancer through to randomized, placebo-controlled Phase IIb clinical trials.

The lead products are Cell Vaccines based on combinations of inactivated tumor cell lines selected from proprietary cell banks. Cell Vaccines induce strong immune responses to a broad spectrum of targets on tumor cells. They are manufactured in bulk under standardized and optimized conditions. Onyvax believes this approach will be effective against many types of solid cancers.

Onyvax is based in London and has collaborations with leading institutions in Europe and the US. Onyvax is committed to the commercialization of new therapies that significantly prolong survival while maintaining a high quality of life for cancer patients.

Technology

Onyvax has taken a number of steps to minimize risk in the development of cancer vaccines. Firstly, Cell Vaccines target a broad range of different cancer antigens. Cancer is a difficult disease to tackle because tumor cells mutate over time and tumors, therefore, consist of a mixture of different cells. This means that any one antigen may be expressed in some cells and not in others. By targeting a very large number of antigens, Cell Vaccines minimize the risk the patient's tumor will mutate and become resistant to the therapy.

Secondly, Onyvax is developing its Cell Vaccines only in patients with a minimal disease burden. Tumors produce molecules that suppress the immune system. The more advanced the cancer, the more immunosuppressed the patient is and the less likely that patient will respond to cancer vaccine therapy. By working in patients with virtually undetectable disease, Onyvax is increasing the chances of clinical success with its Cell Vaccines.

Onyvax's Cell Vaccines have demonstrated encouraging signals of efficacy in open label clinical trials. Randomized, placebo-controlled clinical trials are underway to confirm this effect. Cell Vaccines have an excellent safety profile – the most common side effects being mild, transient flu-like symptoms and irritation at the site of injection. Onyvax's Cell Vaccines have substantial commercial benefits compared to patient-specific (autologous) approaches – each Cell Vaccine can be manufactured on an industrial scale, thereby guaranteeing cost-effective supply. During manufacture of the Cell Vaccines the cells are inactivated so they cannot proliferate in the human body.

Products

Onyvax-P for prostate cancer is currently the subject of three randomized, controlled Phase IIb studies in patients who have no radiologically detectable disease. The first is a European placebo trial in non-metastatic, hormone resistant prostate cancer. The second, in partnership with the NCI, is in patients who have a rising PSA after primary therapy. The third, in partnership with the Mayo Clinic, is investigating the effect of delivering the vaccine via ex-vivo expanded dendritic cells versus standard intradermal injection.

In a previous Phase IIa proof-of-principle study, primary endpoints were met (Clin Cancer Res (2005) 11:4469-4478): the median progression free survival was 58 weeks, which compares favorably with historic control data of 26-29 weeks. 42% patients experienced a prolonged, statistically significant reduction in prostate specific antigen velocity (independent studies have shown PSA velocity to be a predictor of overall survival). The treatment was very well tolerated and side effects were minimal.

An earlier Phase I/II study in advanced metastatic disease demonstrated safety, tolerability and immunogenicity, with patients showing increased T-cell and antibody responses against tumor targets. These patients had disease that was too advanced to see the full effect of the treatment.

Business Strategy

Onyvax is building a portfolio of Cell Vaccines targeting major cancers with significant unmet needs, the most advanced of these is Onyvax-P for the treatment of prostate cancer. As part of the process, the company continues to develop its proprietary bank of human cell lines to comply with the most stringent regulatory standards. The product development strategy is to take its lead drugs through to at least Phase II studies to establish proof-of-principle before partnering with larger pharmaceutical and biotechnology companies.

Markets

- 467,000 new cases of prostate cancer are diagnosed per year in the US, Europe and Pacific Rim. (*American Cancer Society (2003) and International Agency for Research on Cancer (WHO), GLOBOCAN 2000*)
- Cases of prostate cancer in the UK increased 25% between 1995 – 2000. (*UK Association of Cancer Registries*)
- For men with prostate cancer who have become resistant to hormone therapy, median survival is approximately 24 months.
- 119,000 new cases of ovarian cancer are diagnosed per year in the US, Europe and Pacific Rim. (*American Cancer Society (2003) and International Agency for Research on Cancer (WHO), GLOBOCAN 2000*).

Onyvax-O Onyvax has entered into a collaborative license agreement with the Mayo Clinic granting Onyvax exclusive worldwide rights to develop and commercialize a cancer vaccine for ovarian cancer. Manufacturing of GMP master cell banks has been conducted by the National Biomanufacturing Centre (UK), funded by the Northwest Development Agency. Clinical trials are expected to commence in 2009.

Onyvax-105 made from a human monoclonal antibody induces immune responses against a target (CD55) found on many major cancers. CD55 is produced by cancer cells to protect them from immune attack. A number of clinical studies have been conducted in colorectal cancer and osteosarcoma (Br J Cancer (2005) 92:1358-65). Further development is planned both as a monotherapy and in combination with Onyvax-P in prostate cancer.

Product	Cancer type	Status
Onyvax-P	Prostate	Phase IIb
Onyvax-O	Ovarian	Cell Banking
Onyvax-105	Multiple	Physician trials complete