DCVax-Brain for glioblastoma multiforme – newly diagnosed

August 2008

This technology summary is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes.

The National Horizon Scanning Centre Research Programme is part of the National Institute for Health Research
DCVax-Brain for glioblastoma multiforme – newly diagnosed

**Target group**
- Glioblastoma multiforme (GBM) – newly diagnosed.

**Technology description**
DCVax-Brain (DCVax-L) is an immunostimulant cancer vaccine. The company report that DCVax-Brain stimulates the immune system teaching the T-cells and antibodies to recognise and kill the patient’s own tumour. The vaccine is manufactured using a patient’s dendritic cells loaded with a tumour cell lysate prepared from surgically resected tumour tissue. It is intended that DCVax-Brain will be used as an adjuvant to current treatment including primary surgery, carmustine or temodal. The resulting patient-specific DCVax-Brain is administered by injection at weeks 0, 2, 4 and months 2, 4, 8, 12, 18, 24, 30 and 36.

DCVax is in Phase I/II trials for ovarian cancer (DCVax-L).

**Innovation and/or advantages**
If licensed, DCVax-Brain would be the first therapeutic cancer vaccine for GBM.

**Developer**
Northwest Biotherapeutics.

**Availability, launch or marketing dates, and licensing plans:**
In phase III clinical trials.

**NHS or Government priority area:**
This topic is relevant to the NHS Cancer Plan (2000).

**Relevant guidance**
- NICE technology appraisal. Carmustine implants and temozolomide for the treatment of newly diagnosed high grade glioma. 2007².
- NICE technology appraisal. Temozolomide for the treatment of recurrent malignant glioma. 2001³.
- NICE Cancer Service Guidance. Improving outcomes for people with brain and other central nervous system tumours. 2006⁴.

**Clinical need and burden of disease**
Malignant glioma is the most common form of brain tumour, representing 50-60% of all primary brain tumours³. There are three main types of glioma: astrocytoma, ependymoma and oligodendroglioma. Brain tumours are graded according to their likely rate of growth, from grade I (slowest growing) to grade IV (fastest growing), with grades III and IV considered high-grade gliomas. Grade IV astrocytoma is also known as glioblastoma multiforme (GBM)⁵.

The annual incidence of malignant brain tumours in people aged ≥15 years, in England and Wales is 8.5 per 100,000 population (about 3,500 new cases each year). Approximately 1,860 new cases of malignant glioma are diagnosed each year in England.
and Wales. GBM accounts for approximately 40–45% of high grade gliomas\(^5\), around 740 to 840 cases a year.

Brain cancer is more common in males, with a male:female ratio of around 3:2\(^5\). In 2005, 2,953 registered deaths from brain cancer were reported\(^6\). The median survival of patients with GBM is 10 to 12 months from initial diagnosis\(^5\).

**Existing comparators and treatments**
- Surgical resection (rarely curative).
- Radiotherapy.
- Chemotherapy e.g. temozolomide, camustine implants.

**Efficacy and safety**

<table>
<thead>
<tr>
<th>Trial code</th>
<th>NCT00045968: DCVax-Brain vs. placebo; phase II(^7).</th>
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</thead>
<tbody>
<tr>
<td>Sponsor</td>
<td>Northwest Biotherapeutics.</td>
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<tr>
<td>Status</td>
<td>Ongoing</td>
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<tr>
<td>Location</td>
<td>USA</td>
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<tr>
<td>Design</td>
<td>Randomised, double blind, placebo controlled.</td>
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<tr>
<td>Participants in trial</td>
<td>n=270(^a) (estimate); newly diagnosed unilateral GBM (grade IV). Randomised to: two intradermal injections of DCVax-Brain or autologous placebo on days 0, 10, 20 and at weeks 8, 16, 28, 48, 72, 96, 120 and 144.</td>
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<tr>
<td>Follow-up</td>
<td>32 months.</td>
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<tr>
<td>Primary outcome</td>
<td>Progression free survival and overall survival (OS).</td>
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<tr>
<td>Secondary outcomes</td>
<td>OS; time to disease progression; immune response.</td>
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<tr>
<td>Expected reporting date</td>
<td>Confidential.</td>
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</tbody>
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**Estimated cost and cost impact**

The cost of DCVax-Brain is yet to be determined.

**Potential or intended impact – speculative**

**Patients**
- Reduced morbidity
- Quicker, earlier or more accurate diagnosis or identification of disease
- Reduced mortality or increased survival
- Other:
- Improved quality of life for patients and/or carers
- None identified

**Services**
- Increased use
- Decreased use
- Service reorganisation required
- Other:
- Staff or training required
- None identified

**Costs**
- Increased unit cost compared to alternative
- New costs: adjunct to current treatment
- Increased costs: more patients coming for treatment
- Savings:
- Increased costs: capital investment needed
- Other:

\(^a\) Information from the company.
References