brainstrust
the brain cancer people

know how

Immunotherapy DCVax® – information for patients and carers

brainstrust information sheet

Know Hows are published by *brainstrust* to help people living with a brain tumour to understand current topics. They are produced with input from relevant scientific and clinical experts and are written in a way that should help you to understand often complicated topics.

If you have an idea for a Know How, then please let us know.

If you have any queries, don't forget you can talk to one of our support specialists on **01983 292 405** or email **hello@brainstrust.org.uk**.

Why do we need this Know How?

Brain tumour immunotherapy, particularly DCVax®, is gaining an increasing amount of media coverage and interest. We are seeing a growing number of calls to our brain tumour support helpline about DCVax® and brain tumour immunotherapy. This Know How sheds some light on the current state of play for one particular brain tumour immunotherapy trial and some recently published results.

What is immunotherapy?

Immunotherapy is a broad term used for one way of treating cancer. It harnesses the power of the body's immune system to treat cancer. There has been some promising reports of a particular type of immunotherapy having an impact on brain cancer. This immunotherapy is called DCVax® and is produced by a biotech company called Northwest Biotherapeutics (NWB).

What is DCVax®-L?

DCVax®-L is an immune therapy made from each patient's dendritic cells and the specific signature of their glioblastoma (GBM). Dendritic cells are a type of immune cell that help the body's immune system recognise and attack foreign invaders, or antigens. An invading microbe or pathogen is called an antigen. It is seen as a threat by the immune system and can stimulate an immune response. When an antigen enters the body, the immune system produces antibodies against it. This prompts the body's own immune system to attack the GBM tumour. When reintroduced into the body, the DCVax®-L dendritic cell vaccine educates the immune system about which antigens to attack.

What stage is the research currently at?

Interim results from a phase 3 clinical trial were released in May 2018. This trial enrolled 331 patients from the UK, the USA and Canada. An additional update on the phase 3 trial was shared at the Society for Neuro-Oncology annual meeting in November 2018. Phase 3 is the final phase in the clinical trial process prior to registration (enabling doctors to prescribe). If the trial is successful, then the company will seek regulatory approval.

What do these interim phase 3 clinical trial results tell us?

Median survival for people living with GBM who have the current standard of care is 15 months. These interim results show a median survival of 23.1 months for the overall trial population, which includes both the treatment and control arms. The top 100 of the 331 total trial patients on the trial showed a median survival of 58.4 months. Median survival is the time – expressed in months or years – at which half the patients are expected to be alive. It means that the chance of surviving beyond that time is 50%.

At this stage, we don't know which of these patients received DCVax®-L or standard care.

According to Northwest Biotherapeutics, DCVax®-L has shown an excellent safety profile and is very easy to administer by an injection (similar to a flu shot).

What are the next steps for this therapy?

The phase 3 trial is fully enrolled and is not accepting new patients. The data is continuing to mature.

When will this therapy be available?

We don't know. There are many reasons why this is. Some of these are to do with trial development; some are more pragmatic and are to do with making the vaccine.

What can I do if I want to access this treatment in the UK now?

DCVax®-L can be accessed privately on a very limited compassionate-use basis under the Specials regulation in the UK. Please discuss with your clinical team and ask them to contact NWB. You can contact NWB here:

Contact Northwest Biotherapeutics:
www.nwbio.com/contact-us/
Phone +1-240-497-902

I have the funds. Why can't I access this treatment?

Right now, DCVax®-L can only be made available to patients on a very limited basis through the UK Specials programme, as there is currently no regulatory approval. This is down to capacity. If NWB was to make it for everyone who wanted it and could afford it, then the company would need to halt the trial in order to meet the demand. This would not be beneficial in the long term for the wider community.

I've heard there's a waiting list. What is this, and how can I get on the waiting list?

There is a backlog of patients interested in receiving DCVax®-L in the UK through the Specials programme. Please consult with your clinician regarding all available treatment options, and have your doctor contact NWB to see if you are a potential candidate for DCVax®-L.

Is this treatment available for children?

As far as we are aware, no. These results are from an adult trial, and we are not aware of any plans to trial DCVax®-L for children with glioblastoma.

Will DCVax®-L work for other types of brain cancers/tumours?

DCVax®-L is designed to treat all types of operable solid tumours, but the current phase 3 trial is for patients with a newly diagnosed GBM. NWB previously conducted a small phase 1 trial evaluating DCVax®-L in metastatic ovarian cancer and was cleared by the Federal Drugs Agency (FDA) to conduct a phase 3 trial in prostate cancer using DCVax®-Prostate.

For more information, go to
www.nwbio.com

What is the evidence?

DCVax®-L is looking promising. It is going to be a while before this treatment is potentially accessible. The interim results published in May 2018 make interesting reading. This is some of what we know:

- The study took 7 years to recruit 331 patients (there was a 2-year funding gap).
- 1,599 patients were screened for the trial:
  - 306 patients were ineligible for the trial because pathology analysis of tumour tissue confirmed the patient did not have a GBM.
  - A further 250 screened patients showed possible evidence of disease progression prior to being randomised and so could not join the trial. NWB elected to follow 55 of these patients in an 'information arm' (outside of the phase 3 trial). Results for this population of patients, who typically do poorly, were encouraging.
  - 337 patients did not successfully make the vaccine, mainly due to insufficient viable tumour tissue.
  - 331 patients enrolled in the trial, so 20.7% of patients who were screened.
- Those patients who have a good surgical resection of the tumour tend to do better.
- Surgery is a good treatment for GBM – those with gross total resection (which is more likely in the frontal lobe) tend to do well. But this might be down to the surgeon rather than the treatment.

See our commentary here: brainstrust.org.uk/therapies/#3

What does this mean?

Bottom line?

It's a promising treatment for patients with operable, newly diagnosed GBM. At the moment it is not available.

Ask yourself

- What specifically am I struggling with?
- What do I want to know?
- What have I found out for myself?
- What makes it hard?
- What's on the horizon?
- What are the sources of information that will help me fill in the gaps?
- Who can help me?
- How can *brainstrust* help me?

Contact **hello@brainstrust.org.uk** or call **01983 292 405** if you'd like to speak to someone.

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Production of *brainstrust*'s information is supported by the Anna Horrell fund. Anna, wife and mum, tragically passed away in August 2017 after a valiant fight against a glioblastoma. Throughout her life and her illness, she was an inspiration to us all, fighting bravely and cheerfully in the face of adversity. She was the beating heart of our family, and her loss left a hole in our lives that can never be replaced. In her incredible memory, we are passionate about helping others diagnosed with a brain tumour to navigate this most difficult of journeys.

Mike, Tom, Rebecca, Charlie & Sophie