NEWS RELEASE

20th EORTC-NCI-AACR SYMPOSIUM on "Molecular Targets and Cancer Therapeutics" Geneva, Switzerland, 20-24 October 2008

Embargoed: 00.01 hrs CEST, Friday 24 October 2008
NB: this will be the subject of a news briefing by Dr Richard Harrop at 12.15 hrs CEST on Thursday 23 October in the press conference room (Room F in Hall 2)

Cancer vaccine shows promise in patients with bowel, kidney and prostate cancer

Geneva, Switzerland: Analysis of data from several phase I and II clinical trials of a new cancer vaccine has shown it is capable of eliciting an immune response in most patients with bowel, kidney and prostate cancer, and that it may provide clinical benefit.

In a news briefing at the 20th EORTC-NCI-AACR [1] Symposium on Molecular Targets and Cancer Therapeutics in Geneva yesterday (Thursday 23 October), Dr Richard Harrop, vice-president of clinical immunology at Oxford Biomedica, a UK-based biotechnology company – said: "Our exploratory analyses of data from nine different trials of TroVax® demonstrate significant associations between immune responses and overall survival in patients with colorectal cancer, renal cancer and prostate cancer.

"While it is essential that these observations are confirmed in large, randomised studies, collectively the data suggest that TroVax could provide some clinical benefit to cancer patients. In addition, the data show the vaccine is well tolerated by patients."

TroVax is made up of a modified virus (Modified Vaccinia Ankara (MVA)), which acts as a vehicle to transport a second component, a gene that produces an antigen that is present in most solid tumours, called 5T4. TroVax is injected into patients whose solid tumours have the 5T4 tumour antigen present, so that the vaccine can trigger the body's natural immune responses to mobilise against 5T4.

"The virus acts as both a 'vehicle' to deliver the 5T4 antigen and as an 'adjuvant', which helps to ensure we stimulate a strong immune response to the 5T4 antigen," explained Dr Harrop. "Antibody and cellular responses can occur in response to both the viral vector (MVA) and to the 5T4 antigen."

The analysis, presented at the symposium in Geneva, looked at data from 189 patients who had taken part in nine trials of TroVax in the UK and USA. The patients received an average of five injections (with a range of 1-12), and it was well tolerated by patients when given either on its own or in combination with other anti-cancer treatments. Of 180 patients tested for antibody responses after vaccination, 88% (159) showed positive responses to 5T4 and 98% (176) showed positive responses to MVA.

The highest levels of antibody responses were detected after an average of two vaccinations for the MVA part of the vaccine and after four for 5T4. Dr Harrop said: "This was expected because MVA is a foreign virus which the immune system responds to more quickly than to a 'self antigen' such as 5T4."

He continued: "When looking at the results from all the trials (colorectal, renal and prostate cancer patients), the magnitude of the 5T4-specific antibody response was associated with increased patient survival. Indeed, a doubling of the average number of antibodies in the patients between the first and third injections was associated with a reduction in the relative risk of death of 17%. This effect was strongest in colorectal cancer patients.

more/

"Both the magnitude and the frequency of immune responses elicited against our tumour target (5T4) are exceptionally high and could be considered 'best in class'. Since cancer vaccines rely on the induction of immune responses to be able to work, this is a very important attribute of TroVax."

Cancer vaccines have been criticised in recent years because they usually fail to live up to their early promise. Apart from the vaccines against cervical cancer and Oncophage™ (vitespen, approved in Russia for the treatment of kidney cancer), there are no other licensed cancer vaccines. Dr Harrop said there were a number of reasons for this, which included the tools used to assess efficacy, the fact that vaccines on their own are more likely to slow disease progression or clear small tumours rather than cause large reductions in tumour burdens, and the fact that they are probably more likely to work in patients with early stage disease but have to be tested in patients with late stage cancer and large tumour burdens.

"To run a trial in patients with early-stage disease is extremely time-consuming and costly and therefore impossible for most small biotech companies. We are fortunate in this matter in that we have backing from a UK consortium (QUASAR) and our partner sanofi-aventis to run a large (over 3000 patients) phase III study in early stage colon cancer patients. Such a large study would normally be out of the question for a company of our size and is a great opportunity to investigate whether there is a survival advantage in patients treated with TroVax," he said.

"At this stage we can say that the fact we have been able to identify correlations between the anti-tumour (5T4) immune response and clinical benefit (e.g. increased time to disease progression or increased patient survival) in multiple independent trials for several cancers is very encouraging. It gives a strong indication that the immune response we are inducing with TroVax appears to be doing something which is associated with benefit to the patient."

In addition to the phase III trial in early stage colon cancer patients, the effect of TroVax is being monitored in a current phase III trial of 733 kidney cancer patients. Although a recent review by the independent Data Safety Monitoring Board (DSMB) noted that this study would not meet its pre-defined primary endpoint (overall survival) the DSMB strongly supported continuation of the follow-up of the patients.

"We are very hopeful that further phase III studies will provide an opportunity to demonstrate that TroVax can provide clinical benefit to patients without the often severe side-effects which are associated with many cancer therapeutics," concluded Dr Harrop.

(ends)

Abstract no: 601. Poster session in the poster area, 12.00-15.00 hrs CEST, Friday 23 October.

Notes:
[1] EORTC [European Organisation for Research and Treatment of Cancer, NCI [National Cancer Institute], AACR [American Association for Cancer Research].

Further information:
Emma Mason (media information officer)
Tel: +44(0)1376 563090
Mobile: +44(0)7711 296 986
Email: wordmason@mac.com

Emma Ross (media information officer)
Tel : +44(0)20 7233 6266
Mobile: +44 (0)7590 563 314
Email: emmalross@mac.com

From 09.00 hrs CEST Tuesday 21 October to 14.30 hrs CEST Friday 24 October
EORTC-NCI-AACR symposium press office:
Tel: +41 22 761 21 05 Fax: +41 22 761 21 06