



May 2016, Melbourne Australia; Cancer Trials Australia (CTA) released today a summary of a presentation made at the American Association for Cancer Research:

**New RAF-targeted Therapeutic Shows Early Promise against Tumours
With BRAF and RAS Mutations**

Drs. Jayesh Desai¹, Ben Soloman² and Hui Gan³ have established a highly successful collaboration with high-profile Chinese biotech company BeiGene to undertake early phase clinical trials investigating the effect of new investigational cancer therapies for the treatment of patients with a range of types of cancer.

Results from a recent study with the new investigational therapy BGB-283 were presented by Dr. Desai in a Clinical Trials Plenary session at the prestigious American Association for Cancer Research (AACR) on 17 April 2016. Dr. Desai had the honour of being invited to present at this meeting which is one of the biggest and most well attended cancer conferences held in the US.

The new investigational therapy used in this study, BGB-283, that targets the RAF and RAS family of proteins, was found to be safe, tolerable, and showed signs of clinical activity in patients who had a range of cancers with mutations in BRAF, KRAS and NRAS.

A total of 31 patients with advanced BRAF, N- or KRAS mutant solid tumours, who would otherwise have no treatment options, were given varying doses of BGB-283 in a phase I first-in-human, dose escalation and expansion trial. Amongst the 29 patients who were evaluable for a response, three had confirmed partial responses, one had an unconfirmed partial response, and 14 had stable disease. These responses were seen in patients with melanoma, endometrial cancer, thyroid cancer and non-small cell lung cancer. All partial responses were ongoing with the duration of response lasting over 200 days at the time of data cutoff, except for the patient with endometrial cancer who experienced progression-free survival of 455 days.

Results from this study were very encouraging especially with particular respect to seeing anti-tumour activity against RAS-mutant cancers which are traditionally difficult to treat. According to the National Cancer Institute, more than 30 percent of all human cancers, including a large percentage of pancreatic, lung and colorectal cancers, are driven by RAS mutations, but so far, researchers have been unable to develop effective therapeutics to block mutant RAS proteins. Further clinical trials are planned to confirm the results from this study in larger numbers of patients.

Following this initial collaboration with BeiGene, three additional first-time-in human (FTIH) are being investigated across a number of CTA sites which will result in a number of subsequent cancer clinical trials.

The strong collaboration between investigators and member sites of CTA, high quality trial units and the sophistication of personalized medicine in Australia continue to attract investment and engagement from BeiGene for early phase human research. This, in conjunction with current R&D incentives, makes Melbourne an attractive place for overseas Sponsors and Biotech companies.

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² PeterMacCallum Cancer Centre

³ Austin Health Hospital

About Cancer Trials Australia (CTA)

CTA is a Clinical Trial Network and Site Service Organisation providing multisite trial administration and research governance and advisory services to investigators and sponsors of clinical trials in the field of oncology and hematology. Its member organisations are:

Alfred Health
Austin Health
Ballarat Health Services
Barwon Health
Bendigo Health
Border Medical Oncology
Cabrini Health Limited
Chris O'Brien Lifehouse
Melbourne Health
Monash Health
Olivia Newton John Institute for Cancer Research
Peninsula Oncology Centre
Peninsula Health
Port Macquarie Base Hospital
Peter MacCallum Cancer Centre
Royal Women's Hospital
St Vincent's Health
The Walter and Eliza Hall Institute
Tweed Heads Hospital
Western Health
Warrnambool Hospital

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