

ASX ANNOUNCEMENT

Multiple Tribetarna™ treatment produces significantly increased survival in non-small cell lung cancer *in vivo*

Highlights

- Tribetarna™ (a ddRNAi-based therapeutic) provides significantly increased survival in a preclinical *in vivo* model of lung cancer
- After 6 weeks 78% of animals dosed with a combination of Tribetarna™ and cisplatin lived, compared with only 20% of the animals in the control groups
- Study confirms previously reported results that silencing the gene target of Tribetarna™, beta III tubulin, overcomes the resistance of NSCLC tumours to chemotherapy
- Preliminary submission filed with the US FDA

Sydney Australia, 18 December 2013: RNAi-based therapeutics company Benitec Biopharma Limited (ASX Code: BLT) today announced the results of pre-clinical experiments confirming the ability to significantly increase survival in non-small cell lung cancer (NSCLC) *in vivo*. The research was performed by the Company's collaboration partner, the Children's Cancer Institute Australia (CCIA) at the University of New South Wales, Sydney, Australia (UNSW).

The data showed that in a mouse model of human lung cancer, where human lung cancer cells form tumours in the lungs of mice, the animals that were treated with Tribetarna™, Benitec's gene silencing therapeutic, and cisplatin (the mainstay chemotherapy drug used for advanced NSCLC), survived significantly longer ($p < 0.0001$) than those that were treated with cisplatin alone. Unlike the previously reported experiments, the mice received multiple doses of Tribetarna™ and cisplatin. As a result, after 43 days, 78% of the animals dosed with Tribetarna™ and cisplatin were alive, compared with only 20% of the animals in the control group, that received cisplatin alone or in combination with a non-specific construct.

The CCIA researchers have demonstrated previously that the gene target of Tribetarna™, beta III tubulin, is strongly associated with the resistance of NSCLC tumours to chemotherapy.

"The orthotopic model we used in these experiments consists of human NSCLC cells grown in the lungs of mice, and closely mimics the human situation," Professor Maria Kavallaris of CCIA explained. "These human NSCLC cells are strongly resistant to chemotherapy normally, and we were able to demonstrate that three cycles of intravenous administration of Tribetarna™, in combination with a standard chemotherapy drug, cisplatin, was able to significantly extend the survival of the animals," she added.

Benitec's CEO, Dr Peter French commented: "Tribetarna™ appears to offer a new option to overcoming chemotherapy resistance, and thus could be a novel approach to enhance the efficacy of chemotherapy drugs and to increase patient survival."

As a result of these very encouraging data, Benitec have submitted a preliminary application to the United States Food and Drug Administration (USFDA) seeking guidance on the optimum design of IND-enabling toxicity and biodistribution studies for this novel, systemic approach leading to a planned first-in-man clinical trial late in 2014. The USFDA have indicated that a teleconference will be scheduled towards the end of February to discuss the submission.



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About Benitec Biopharma Limited: Benitec Biopharma Limited is an ASX-listed biotechnology company (ASX Code: BLT) based in Sydney, Australia. The company has a pipeline of in-house and partnered therapeutic programs based on its patented gene-silencing technology, ddRNAi. Benitec is developing treatments for chronic and life-threatening human conditions such as Hepatitis C, Hepatitis B, wet age-related macular degeneration, cancer-associated pain, drug resistant lung cancer and oculopharyngeal muscular dystrophy based on this technology. In addition, Benitec has licensed ddRNAi technology to other biopharmaceutical companies who are progressing their programs towards the clinic for applications including HIV/AIDS, retinitis pigmentosa and Huntington's disease. For more information on Benitec refer to the Company's website at www.benitec.com.