

ASX RELEASE

Clinical study confirms Benitec's gene-silencing technology is safe and effective in Gradalis' cancer vaccine

Sydney, January 10, 2012

The Directors of Benitec Biopharma Ltd (ASX:BLT) are pleased to announce the publication in *Molecular Therapy* by researchers from US-based Gradalis Inc. and academic research centres, of completed Phase I clinical trial results of a novel cancer vaccine (FANG) which in part utilised Benitec Biopharma's patented gene-silencing technology, DNA-directed RNA interference (ddRNAi).

The trial evaluated the vaccine in patients with advanced or metastatic non-curable solid tumours, including melanoma, colon, breast, liver, bile duct and colon cancers. The patients received up to twelve monthly intradermal injections of FANG vaccine. The investigators concluded that "the vaccine was safe and elicited an immune response correlating with prolonged survival. Phase II assessment is justified."

In summary, the trial results demonstrated:

- That the ddRNAi component (a bi-shRNA molecule) was effective at significantly reducing the immunosuppressive cytokines TGF-β1 and -β2 by up to 93.5% and 92.5%, respectively
- That the GM-CSF gene component of the vaccine was effective at boosting the proimmune cytokine GM-CSF.
- The combined approach of inhibiting expression of immunosuppressive TGF-β isoforms via a bi-shRNA-mediated knock-down along with an integrated GM-CSF + RNAi treatment was feasible and effective
- That despite this being a Phase 1 study, there was a significant survival advantage seen for those cancer patients who had 4 or more treatments of the FANG vaccine compared to those who had fewer or no treatments.
- The safety and tolerability of the FANG vaccine as shown by the lack of any treatment-related serious adverse effects.

The authors commented that:

"These results confirm FANG vaccine safety and in addition provide a phase I database justifying continued clinical evaluation and expansion of immune assessment assays. To this end, a phase II trial in melanoma patients with biopsy accessible advanced disease ... has recently been initiated (BB-IND 14205, CL-PTL 114)."

In response, Chief Executive Officer of Benitec Biopharma Dr Peter French commented, "The data from this human trial are very impressive, given the advanced stage and broad range of the cancers on which the vaccine was tested. This study further expands the extensive body of literature that demonstrates the potential of Benitec Biopharma's ddRNAi technology to form the basis of safe, effective, systemically-delivered transformational therapeutics for a range of diseases which are only limited by the imagination and expertise of scientists and clinicians globally. We certainly look forward to the Phase II clinical trial results from this group".



For Further Information

Dr Peter French

Chief Executive Officer

Tel: +61 (0)412 457 595

pfrench@benitec.com

www.benitec.com

About Benitec Biopharma

Benitec Biopharma Ltd is developing novel treatments for chronic and life-threatening conditions based on targeted gene-silencing activity using a transformational technology: DNA-directed RNA interference (ddRNAi) - sometimes called expressed RNAi. The technology's potential to address unmet medical needs and to cure disease results from its demonstrated ability to permanently silence genes which cause the condition. Importantly, this technology's target gene and related gene pathways will rarely have presented as a therapeutic avenue for research for the traditional small molecule agents, currently accounting for the majority of today's pharmaceutical products.

Benitec Biopharma now either owns or exclusively licenses from CSIRO more than 40 granted or allowed patents in the field of RNA interference for human therapeutic applications. Patents have been granted in key territories such as the USA, the UK, Japan, Europe, Canada and Australia. In addition, Benitec Biopharma has almost 50 patent applications pending for which it is the owner or exclusive licensee from CSIRO, and has further intellectual property under development as a result of its pipeline program.

Founded in 1997 and trading publicly since 2001, Benitec Biopharma is listed on the Australian Securities Exchange (ASX) under the symbol "BLT". Benitec Biopharma aims to deliver a range of novel ddRNAi-based therapeutics to the clinic in partnership with the pharmaceutical industry. In addition to its focused R&D strategy in infectious diseases, cancer and chronic cancer-associated pain, Benitec Biopharma is pursuing programs with licensees.

Reference

Senzer N, Barve M, Kuhn J, et al. Phase I Trial of "bi-shRNA^{furin}/GMCSF DNA/Autologous Tumor Cell" Vaccine (FANG) in Advanced Cancer *Molecular Therapy* , (20 December 2011) | doi:10.1038/mt.2011.269

Information about Gradalis Inc can be gained from their website (gradalisinc.com).