

Benitec Biopharma Ltd ABN 64 068 943 662 F6A / 1-15 Barr Street Balmain NSW 2041 Australia Tel: +61 (0) 2 9555 6986 Email: info@benitec.com www.benitec.com

ASX ANNOUNCEMENT

Benitec Selects the Duke Clinical Research Unit as a Site for Hepatitis C Phase I/II Clinical Trial

Sydney Australia and Durham, North Carolina, USA, 22 March 2013: RNAi-based therapeutics company Benitec Biopharma Limited (ASX Code: BLT) today announced the selection of the Duke Clinical Research Unit, the early phase unit of the Duke Clinical Research Institute (DCRI) (Durham, North Carolina, USA as a site for its upcoming phase I/II first-in-man trial for TT-034 in Hepatitis C. TT-034 is being developed as a potential "one-shot-cure" for Hepatitis C (HCV).

"We are very excited to be working with Duke, a world renowned research institution with significant experience in this area," said Peter French, Ph.D., Chief Executive Officer of Benitec. "The TT-034 trial marks the transition of Benitec to a clinical stage company. We expect that positive results from the trial will provide a value inflection point for the company, and also be a validation for our ddRNAi technology as an effective platform for therapeutics."

The phase I/II clinical trial is an open-label dose escalation study to evaluate the safety and activity of single doses of TT-034 in patients with chronic HCV genotype 1 infection who have failed previous treatments. The trial is expected to involve 14 patients in 5 sequential dose cohorts. Additional consolidation cohorts may be added during the study to confirm the results of the trial. The primary safety endpoints are dose limiting adverse events. The primary activity end points are serum viral load reduction and degree of hepatocyte transduction (measured through liver biopsies). There is a pre-specified interim read on safety and activity within months of trial commencement. The clinical trial is expected to begin enrolling patients during the second half of 2013.

Duke's principal investigator for the study will be Keyur Patel, M.D. Dr Patel has previous experience with oligonucleotide therapeutics in HCV, is a recipient of the prestigious American Association for the Study of Liver Diseases (AASLD) Shelia Sherlock Clinical and Translational Research award and has over 100 citations in peer-reviewed publications.

"TT-034 is a potentially transformative new treatment," Dr. Patel commented. "A therapeutic that could cure an HCV patient with a single injection would obviously be a big step forward compared to even the best treatments that are currently on the horizon, as they all involve comparatively lengthy regimens with a combination of several drugs."

About TT-034

TT-034 is a potentially transformative therapeutic that is intended to provide a "one-shotcure" for Hepatitis C with a single injection. TT-034 works through RNA interference (RNAi), which is a naturally occurring regulatory process in cells that acts to "silence" genes after they have been transcribed from DNA into messenger RNA. Benitec's proprietary ddRNAi approach involves the introduction of a DNA vector that produces short hairpin RNAs (shRNAs) that are processed by the cell into siRNAs. This approach emulates the cell's own gene silencing mechanism and provides long term activity



(months). Moreover, the virus vector used to deliver the TT-034 construct, an engineered non-replicating adeno-associated virus (AAV8), targets almost exclusively liver cells (where HCV replicates). TT-034 is further designed to prevent viral escape through mutations (a major problem for most HCV drugs) by using three different shRNAs to simultaneously target three separate highly conserved regions in the HCV genome. In mice and monkeys, TT0-034 has been shown to transduce 100% of hepatocytes in the liver and provide high shRNA activity for 180 days (the duration of the studies), without adverse effects.

About the Duke Clinical Research Unit:

The Duke Clinical Research Unit (DCRU) is a state-of-the-art research facility located within the Duke Medicine campus that provides infrastructure support to sponsors and investigators who are testing new drug candidates and other cutting-edge therapies, or seeking to identify and validate novel biomarkers. The DCRU has more than 20 years of early-phase clinical trial experience and has successfully conducted more than 150 earlyphase studies, including 80 phase 1 studies. The experience, support systems and infrastructure of the DCRU enable provision of the highest level of program management and services for early-phase clinical trials, including quality processes, accurate reporting, and regulatory expertise. The DCRU combines the clinical expertise and scientific leadership of one of the most prestigious academic medical centres in the world with the operational capabilities of a full-service contract research organization. The DCRU is part of the Duke Clinical Research Institute. The DCRI is a comprehensive academic research organization and the only one of its kind that can offer all the services of a commercial contract research organization with the academic credibility and expertise of an academic medical center.

About Benitec Biopharma Limited:

Benitec Biopharma Limited (ASX Code: BLT), based in Sydney, Australia, 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. Its most advanced program is TT-034 for the treatment of chronic HCV infection. Benitec has licensed ddRNAi technology to other biopharmaceutical companies who are advancing their programs toward 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 <u>www.benitec.com</u>.

For more information please contact:

For Duke Clinical Research Unit: Barry Mangum, PharmD | Director Clinical Pharmacology Phone: 919 210 8099 | Barry.Mangum@duke.edu| www.dcru.org

For Benitec: Dr Peter French | Chief Executive Officer Phone: +61 (02) 9555 6986 | pfrench@benitec.com | www.benitec.com