

PRESS RELEASE

Benitec Selects University of California, San Diego as a Site for Phase I/II Clinical Trial of TT-034 in Patients with Hepatitis C Infections

Sydney Australia, April 16, 2013: RNAi-based therapeutics company Benitec Biopharma Limited (ASX Code: BLT) today announced the selection of the University of California, San Diego (UCSD), Health Sciences as the second site for its upcoming phase I/II first-in-man trial for TT-034 in Hepatitis C infections (HCV). Benitec previously announced the selection of Duke Clinical Research Unit as the other site. TT-034 is being developed as a potential “one-shot-cure” for HCV.

A consultant and sub-principal investigator for the study from UCSD Health Sciences will be Robert Gish, M.D., clinical professor of Medicine and medical director of Hepatology. Dr. Gish is a renowned hepatitis researcher with previous experience using RNAi based therapeutics for HCV. He has over 500 publications in the field and is a fellow of the American College of Physicians and the American Association for the Study of Liver Disease.

“I look forward to working with Benitec and Duke University on this important program,” Dr. Gish commented. “This is the first time that this therapeutic modality is being tested in humans, and if it is successful I believe it can be a significant step forward, not only for HCV treatment but potentially also as a treatment modality for Hepatitis B.”

The principal investigator for the study at UC San Diego is David Wyles, M.D., associate professor of Medicine at the UC San Diego AntiViral Research Center, the clinical research site that will be conducting the trial. His research interests include the laboratory evaluation of new antiviral therapies for HCV, drug resistance to HCV antivirals, and HCV viral fitness.

Peter French, Ph.D., chief executive officer of Benitec said, “We are elated that UC San Diego and Dr. Gish will participate in this study. We now have two top clinical research teams working with Benitec on this trial. This constellation of expertise will greatly benefit our HCV program and can help demonstrate the power of our ddRNAi technology in the clinic. Having our two clinical centers in place moves us a step closer to initiating the Phase I/II clinical trial, which we expect to occur during the second half of 2013.”

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 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.



About TT-034

TT-034 is a potentially transformative therapeutic that is intended to provide a “one-shot-cure” 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, TT-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 UC San Diego Health Sciences

University of California, San Diego Health Sciences comprises clinical and academic entities – UC San Diego Health System, the region’s only academic health system; UC San Diego School of Medicine, one of the top US research-intensive schools of medicine; and Skaggs School of Pharmacy and Pharmaceutical Sciences. The US National Institutes of Health (NIH) ranks UC San Diego Health Sciences as one of the top institutions in research funding per faculty member, and the School of Medicine is in the top 10 in total NIH research funding. Part of the University of California system, UC San Diego – founded in 1960 – is renowned for collaborative and cross-disciplinary research that transcends traditional boundaries in science, engineering and the humanities.

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 www.benitec.com.

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