

ASX ANNOUNCEMENT

HCV (hepatitis C) clinical trial progress update

Sydney Australia, 8 March 2013: RNAi-based therapeutics company Benitec Biopharma Limited (ASX Code: BLT), is pleased to provide an update on the upcoming Phase I/II trial of its lead therapeutic TT-034 in hepatitis C (HCV) patients. TT-034 is being developed as a potential “one-shot-cure” for HCV.

The planned US-based trial is an open-label dose-escalation study in infected patients, with interim data on safety and efficacy likely within months of trial commencement. Benitec is progressing through the required US regulatory approval process (including Recombinant DNA Advisory Committee (RAC) and Investigational New Drug (IND) filings), enabling the company to commence patient enrolment and dosing in the second half of calendar 2013.

Benitec has been working closely with its US-based contract research organization (CRO) Synteract since January 2013. Synteract was primarily selected as CRO for their capability and experience with RAC submissions and HCV trials, and Synteract’s recently announced merger with Harrison Clinical Research) transforms the merged firm (SynteractHCR) into a top-tier global CRO.

Over the last two months Benitec, together with Synteract have carried out a range of activities aimed at moving the HCV program into the clinic. These activities have included:

- Completion of an in-depth program analysis of requirements for the Recombinant DNA Advisory Committee (RAC) and Investigational New Drug (IND) filings, and requirements for trial commencement. These analyses have confirmed the positive assessment Benitec conducted as part of the Tacere acquisition process in October (2012).
- Evaluation of a number of potential US-based trial sites. Benitec has now confirmed both primary and secondary sites for the proposed trial, providing access to appropriate patient populations and experienced and motivated principal investigators. Both sites have accepted and we are in the process of negotiating clinical trial agreements.
- Completion of the draft clinical trial protocol.
- Completion of the draft patient informed consent form.
- Finalisation of the RAC filing. The submission to RAC will be filed in early April 2013, with a decision to be announced in June 2013.
- Preparation of US FDA IND filing. This filing is similar to the RAC application. It is, however, more extensive and requires validation of a number of tests to measure data from the patients during the course of the clinical trial, such as viral load, changes in HCV sequences and determining penetration levels of TT-034 into liver tissues from the treated subjects. The tests have been reviewed and requirements documented. The IND filing submission will be filed following RAC approval.

Benitec’s CEO, Dr Peter French commented: “We are now well advanced in our preparations for both the RAC and IND filings. While largely process, the US regulatory approval allowing for commencement of the HCV clinical trial is an importation step in Benitec’s transition to a clinical-stage company. We look forward to providing further market updates on the clinical trial progress.”



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About TT-034: TT-034 utilizes a mechanism of action mediated by RNA interference (RNAi), an evolutionarily conserved cellular process for sequence-specific gene silencing. HCV is particularly amenable to this approach as replication of its RNA genome occurs entirely within the cytoplasm of infected hepatocytes (liver cells), the same location of the cell's endogenous RNAi machinery.

TT-034 uses a synthetic DNA expression template to simultaneously express three short hairpin RNAs (shRNAs) that cleave three non-overlapping and well-conserved sequences within the HCV genome, thereby rendering it incapable of further replication and packaging into nascent virions (viral particles). The presence of multiple therapeutic shRNA species may also help prevent the generation of viral escape mutants. The three independent promoters that drive expression of the shRNA have been carefully designed to produce sufficient quantities of shRNA to ensure therapeutic activity, while eliminating toxicity. The expression cassette for TT-034 is delivered via an adenovirus-associated viral vector, known to highly target the liver and known for persistence for months or even years after a single administration of the drug. When administered at certain levels, a single dose of TT-034 was shown in our murine (mouse) and non-human primate studies to transduce nearly 100% of hepatocytes, the sole site of active HCV replication in humans, without any adverse effects and shRNA was persistent out to 180 days, the duration of the study.

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.