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# **ASX ANNOUNCEMENT**

# Benitec appoints Clinical Research Organisation for Hepatitis C clinical trial

## **Key Points:**

- Benitec Biopharma appoints Synteract Inc, a US-based Clinical Research Organisation, with extensive Hepatitis C clinical trial experience
- Synteract Inc will assist in the preparation of regulatory submissions and manage the Phase I/IIa clinical trial for TT-034, a gene silencing therapeutic for treatment of patients infected with the Hepatitis C virus (HCV)
- The appointment is a key milestone in advancing the program into the clinic.

**Sydney, Australia December 18, 2012**: Benitec Biopharma Ltd (ASX: BLT) today announced the appointment of Synteract Inc, a US-based clinical research organisation, as a key step in the clinical development of its HCV therapeutic, TT-034.

Synteract has extensive experience in conducting clinical trials and preparing regulatory submissions in the HCV field. The company has managed numerous projects across all phases of clinical development leading to twenty-two US FDA product approvals.

Synteract have begun work on the project implementation tasks under the direction of Benitec. These activities include assistance in reviewing the clinical trial protocol and compilation of regulatory submissions.

Benitec plans to enter the clinic in 2013 with TT-034, a late-stage preclinical ddRNAi-based gene silencing molecule.

Benitec CEO Dr Peter French commented, "The Board and Management is very pleased to be working with Synteract. Synteract met the extensive criteria for the choice of CRO for our HCV clinical trial process, and we now look forward to progressing TT-034 into the clinic in 2013."

## For more information please contact:

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### **About Benitec Biopharma**

Benitec Biopharma Ltd is developing novel treatments for chronic and life-threatening conditions based on gene-silencing technology which is targeted and transformational, called DNA-directed RNA interference (ddRNAi) or expressed RNAi. The technology's potential results from its demonstrated ability to permanently silence genes that cause the conditions. Importantly, the genes and gene pathways being targeted by ddRNAi have rarely been the subject of therapeutic research using small molecule agents, on which most of today's pharmaceutical products are

Benitec Biopharma trades on the Australian Securities Exchange (ASX) under the symbol "BLT". The company aims to deliver a range of novel ddRNAi-based therapeutics to the clinic in partnership with the pharmaceutical industry. In addition to a focused R&D strategy in infectious diseases, cancer and chronic cancer-associated pain, Benitec Biopharma has licensed its ddRNAi-based gene silencing technology to a number of licensees who are progressing their programs towards the clinic.

#### **About TT-034**

TT-034 is a ddRNAi molecule that was created by Tacere Therapeutics and advanced through the development pathway in collaboration with Pfizer. The molecule is designed to express three independently transcribed short hairpin RNA (shRNA) elements that simultaneously target and cleave three separate regions of the Hepatitis C virus genome, thus helping prevent the generation of viral escape mutants. The targeted viral genome regions are conserved across many genotypes of the virus. TT-034 demonstrates potent inhibition of HCV in the *in vitro* replicon model, and has shown no toxicity *in vitro* or *in vivo*. Thus TT-034 represents a novel combination drug in a single therapeutic entity that provides broad patient applicability, while maintaining exquisite specificity. By harnessing the advances of gene medicine and using a delivery method for macromolecules that has demonstrated safety in clinical trials, TT-034 can be administered via peripheral intravenous infusion. It preferentially enters virtually all of the liver cells in which HCV replicates, and has the ability to confer long-term therapeutic benefit. Benitec acquired Tacere Therapeutics in October 2012, including its HCV and wet AMD ddRNAi-based programs.

#### **About Synteract Inc**

Synteract is a full-service contract research organization with a successful 17-year track record supporting biotechnology, medical device and pharmaceutical companies in all phases of clinical development. With its "Shared Work – Shared Vision" philosophy Synteract provides customized Phase I through IV services collaboratively and cost effectively to ensure on-time delivery of quality data so clients get to decision points faster. Headquartered in California, Synteract delivers trials internationally, offering expertise across multiple therapeutic areas including notable depth in oncology, CNS, cardiovascular, respiratory and ophthalmology.