

BENITEC COMMENCES PATIENT DOSING WITH TT-034 IN PATIENTS WITH HEPATITIS C

Sydney Australia, 29 May 2014: RNAi-based therapeutics company, Benitec Biopharma Limited (ASX: BLT) is pleased to announce that it has dosed the first patient in its ‘first in man’, Phase I/IIa clinical trial for TT-034, a ddRNAi-based therapeutic, designed to treat and potentially cure hepatitis C (HCV) with a single injection.

Benitec Biopharma’s CEO and Managing Director, Peter French said, “The commencement of this clinical trial of TT-034 represents a landmark in the Company’s history. The trial is the first time Benitec’s gene silencing technology, ddRNAi, has been used systemically in patients.

The primary objective of this first trial is to demonstrate that TT-034 can be used safely in patients with HCV. Preclinical work in non-human primates demonstrated very low toxicity results at therapeutically relevant doses, and we’re hopeful that we will see the same favourable tolerability in humans. In addition, we will be able to assess the impact of TT-034 treatment on HCV viral load in these patients, and this important efficacy marker constitutes one of the secondary endpoints of this study.”

The TT-034 Phase I/IIa clinical trial is an open label, dose escalation study in a total of 14 patients chronically infected with HCV genotype 1. Initial patient cohorts will be treated with a sub-therapeutic dose of TT-034 to ensure that there are no unexpected safety concerns, before proceeding to higher, potentially therapeutic doses.

An expert medical panel, the Data Safety Monitoring Board (DSMB), which is independent of Benitec, will carefully assess the data from each patient, in particular the safety data. The DSMB assessment will occur after the first patient in each cohort and between cohorts, and will determine the timing of each subsequent dosing.

Additional detail on the clinical trial design and protocol is included at the bottom of this announcement.

For further information, please contact the persons below, or visit the Benitec website at www.benitec.com.

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About the TT-034 Phase I/IIa Clinical Trial

The TT-034 Phase I/IIa clinical trial is an open label, single dose, dose escalation study in 14 patients infected with genotype 1 hepatitis C virus (HCV.) The trial is comprised of five dose cohorts, organised as follows:

<i>Cohort</i>	<i>Dose (vg/kg)</i>	<i>Dose escalation step (log 10)</i>	<i>Number of Patients</i>	<i>Dosing scheme</i>	<i>Observation period per Patient and between cohorts before dose escalation</i>
1	4.00×10^{10}	Starting dose	2	Sequential (1+1)	6 weeks
2	1.25×10^{11}	0.5	3	Sequential and parallel (1+2)	6 weeks
3	4.00×10^{11}	0.5	3	Sequential and parallel (1+2)	6 weeks
4	1.25×10^{12}	0.5	3	Sequential and parallel (1+2)	10 weeks
5	4.00×10^{12}	0.5	3	Sequential and parallel (1+2)	10 weeks

- Independent Data Safety Monitoring Board review after first patient in each cohort and between cohorts
- Extensive safety monitoring during 24 weeks of observation

Trial sites:

- Duke Clinical Research Unit, North Carolina (Dr. Keyur Patel)
- University of California, San Diego (Dr. David Wyles)

Primary endpoints: safety

- Incidence of treatment-emergent adverse events
- Changes in clinical and laboratory parameters

Secondary endpoints: efficacy

- Sustained reduction in HCV viral load
- Assessment of viral vector DNA levels in liver biopsy
- Assessment of shRNA expression in liver biopsy
- shRNA expression levels in exosomes in serum
- Blood vector DNA levels in serum

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.