

## **BENITEC ANNOUNCES SECOND PATIENT DOSED IN THE TT-034 PHASE I/IIA CLINICAL TRIAL**

**Sydney Australia, 13 November 2014:** RNAi-based therapeutics company, Benitec Biopharma Limited (ASX: BLT, OTC: BTEBY) today announced that the second patient had been dosed 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. The patient was treated with TT-034 at Duke Clinical Research Unit in the United States.

Approval to dose the second patient followed Benitec’s announcement on 21 July 2014 that an independent expert medical panel, the Data Safety Monitoring Board (DSMB), had carefully assessed data, in particular safety data, from the first patient and recommended that the study could continue without modification. The same review process will occur after each patient group.

A third patient has now been identified as suitable for inclusion in the trial. This subject will be dosed provided the patient’s clinical data continues to fall within the criteria and the DSMB determine it is safe to do so after reviewing the response of the second patient to TT-034 over the course of the next six weeks.

The TT-034 clinical trial is an open label, dose escalation study in a total of 14 patients chronically infected with HCV genotype 1. A summary of the trial protocol is appended to this announcement.

For further information, please contact the persons outlined below, or visit the Benitec website at [www.benitec.com](http://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 comprises five dose cohorts, organised as follows:

Cohort	Dose (vg/kg)	Dose escalation step (log 10)	Number of Patients	Dosing scheme	Observation period per Patient and between cohorts before dose escalation
1	$4.00 \times 10^{10}$	Starting dose	2	Sequential (1+1)	6 weeks
2	$1.25 \times 10^{11}$	0.5	3	Sequential and parallel (1+2)	6 weeks
3	$4.00 \times 10^{11}$	0.5	3	Sequential and parallel (1+2)	6 weeks
4	$1.25 \times 10^{12}$	0.5	3	Sequential and parallel (1+2)	10 weeks
5	$4.00 \times 10^{12}$	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:BLT; OTC: BTEBY) which has developed a patented gene-silencing technology called ddRNAi or 'expressed RNAi'. Based in Sydney, Australia with labs in Hayward CA (USA) and collaborators and licensees around the world, the company is developing ddRNAi-based therapeutics for chronic and life-threatening human conditions including Hepatitis C and B, drug resistant lung cancer and wet Age-related Macular Degeneration. Benitec has also licensed ddRNAi to other biopharmaceutical companies for applications including HIV/AIDS and retinitis pigmentosa. For more information visit [www.benitec.com](http://www.benitec.com).