February 16, 2017

Benitec Biopharma to present expanded data set from pivotal data in hepatitis B virus (HBV) in vivo model at International Liver Meeting in Shanghai, China

-- Demonstrates that a single administration of ddRNAi agent can significantly improve HBV suppression in combination with existing anti-HBV therapies

-- Informs clinical development path and defines the potential of a new treatment paradigm

SYDNEY, Feb. 16, 2017 /PRNewswire/ -- Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) today announced that it will present pivotal data from the Company's hepatitis B virus (HBV) *in vivo* model at the 26th Conference of the Asian Pacific Association for the Study of the Liver (APASL) meeting, in Shanghai China. Dr David Suhy, Benitec's Chief Scientific Officer will detail the expanded data set during an oral presentation entitled, 'Combinations of a DNA-directed RNA interference Agent with Standard of Care Drugs Results in Superior Suppression of Hepatitis B Virus (HBV) in a Chimeric Mouse Model.'

Data presented at leading liver conference

This is the first public forum where Benitec will present the expanded data set from the chimeric mouse study results that were initially reported in December 2016. The data demonstrate that a single administration of one of three DNA-directed RNA interference (ddRNAi) agents, BB-101, BB-102 or BB-103, used in combination with current standard of care agents used to treat HBV, demonstrates significantly robust and sustained suppression of the disease in an *in vivo* model.

The APASL conference is an annual event hosted by one of the world's leading associations for the investigation and treatment of liver disease.

A single administration of a ddRNAi agent substantially enhances HBV suppression when used in combination with antiviral agents

This *in vivo* study assessed the activity of single doses of ddRNAi therapeutic constructs BB-101, BB-102 and BB-103 in the PhoenixBio mouse model, in which a substantial portion of the mouse liver cells have been replaced with human hepatocytes making the animals susceptible to HBV infection.

As previously reported in December 2016, when dosed individually in the absence of other anti-viral drugs, a single dose of BB-103 or BB-102 resulted in corresponding maximum drop of serum HBV DNA levels at 2.17 log and 1.87 log reduction. A modest rebound of HBV DNA levels were noted following 56 days of treatment. A treatment arm consisting only of daily entecavir resulted in a 2.63 log drop in serum HBV DNA levels. In combination with daily entecavir, a single dose of BB-103 and BB-102 dropped the serum HBV DNA levels below 3.72 log, the lower limit of quantification (LLOQ) for the assay. The LLOQ represents the lowest value that can result in accurate quantification of HBV DNA levels. Although HBV DNA is detectable below this level, it cannot be quantified. The reduction in viral burden continued to diminish until the end of the 91 day experiment with these combinations. In addition, BB-103 plus entecavir and BB-102 plus entecavir also dropped HBsAg levels, a known contributor to immunosuppression and HBV chronicity, by 2.14 log and 1.86 log. In comparison, treatment with entecavir only dropped HBsAg levels by 0.46 log.

Expanded results from preclinical model demonstrates potential for new treatment options

Benitec's Chief Scientific Officer, Dr. David Suhy said, "It is likely that a combination of drugs will be required to successfully treat the majority of subjects infected with HBV. The ability to apply constant, therapeutic pressure at multiple points within the life cycle of the virus by using a wide variety of drugs is a well established treatment modality for treating many infectious diseases. Thus, there is a race to determine which of the new types of therapeutics being developed can be successfully combined with established drugs to treat HBV. We believe the data being presented, a one time treatment on top of existing therapies, offers a compelling case for the inclusion of a ddRNAi therapeutic into the treatment regimen."

New data helps guide Benitec team for clinical protocol design

In addition to co-treatment with nucleoside analogues, this current study tested combinations of either BB-101, BB-102 or BB-103 when co-administered with pegylated interferon which resulted in a significant decrease in HBV serum DNA levels at 2.67, 2.78 and 3.27 log respectively. This modest drop, as compared to 2.41 log drop from interferon treatment alone, potentially suggests that the mechanism of action of interferon may obstruct or impair the ability of the natural cellular machinery to induce RNA interference.

Georgina Kilfoil, Benitec's Chief Clinical Officer commented, "The results of these experiments will help guide the development of the clinical protocol for the first in man clinical trials of this ddRNAi treatment modality. Clearly co-administration with a nucleoside analogue such as entecavir is useful in the overall treatment regimen, while other therapeutic combinations may be less effective."

Benitec's ddRNAi technology is a unique combination of gene silencing using RNA interference coupled with the long term therapeutic activity of gene therapy vectors. For the HBV program, the lead candidates are comprised of an adeno associated virus capsid (AAV8) and a recombinant DNA cassette engineered to express steady state levels of three short hairpin RNA (shRNA) that inhibit HBV viral RNA at three regions well conserved across all major genotypes.

The full presentation for the APASL meeting is posted on the company's webpage at

www.benitec.com.

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

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About Benitec Biopharma Limited:
Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) is a biotechnology company developing innovative therapeutics based on its patented gene-silencing technology called ddRNAi or 'expressed RNAi'. Based in Sydney, Australia with laboratories in Hayward, California (USA), and collaborators and licensees around the world, the company is developing ddRNAi-based therapeutics for chronic and life-threatening human conditions including hepatitis B, wet age-related macular degeneration and OPMD. Benitec has also licensed ddRNAi to other biopharmaceutical companies for applications including HIV/AIDS, Huntington's Disease, chronic neuropathic pain, cancer immunotherapy and retinitis pigmentosa.

About Hepatitis B: Worldwide, 2 billion people (1 out of 3 people) have been infected with hepatitis B virus (HBV) and 400 million people have become chronically infected, including 1 to 2 million people in the United States. An estimated 1 million people die each year from hepatitis B and its complications worldwide; about 5,000 of those are in the U.S. Worldwide, chronic infection with hepatitis causes 80% of all hepatocellular carcinoma (HCC) and more than 500,000 people die each year from this lethal cancer. About 5% of the population are chronic carriers of HBV, and nearly 25% of all carriers develop serious liver diseases such as chronic hepatitis, cirrhosis, and HCC. Current treatment options include long-term antiviral therapies that permit low-levels of virus cells to replicate leading to HBV viral persistence and affecting therapeutic outcomes. There is a significant need for safe and convenient novel therapeutics that restore host immune response through targeted HBsAg knockdown offering HBV patients the potential for 'functional cures' by eliminating virus producing cells.

Safe Harbor Statement:
This press release contains "forward-looking statements" within the meaning of section 27A of the US Securities Act of 1933 and section 21E of the US Securities Exchange Act of 1934. Any forward-looking statements that may be in the press release are subject to risks and uncertainties relating to the difficulties in Benitec's plans to develop and commercialise its product candidates, the timing of the initiation and completion of preclinical and clinical trials, the timing of patient enrolment and dosing in clinical trials, the timing of expected regulatory filings, the clinical utility and potential attributes and benefits of ddRNAi and Benitec's product candidates, potential future out-licenses and collaborations, the intellectual property position and the ability to procure additional sources of financing. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.

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