



## Media Release

### Benitec's Hepatitis B RNAi Program with Biomics Biotechnologies Moves to the Next Stage Following Successful Stage 1 Results

21 February 2011, Melbourne, Australia: Benitec Limited (ASX:BLT), a world leader in expressed gene silencing for human therapeutics, is pleased to announce that following the success of the first stage of its anti-viral program to develop an RNA interference (RNAi)-based therapy against Hepatitis B virus (HBV), conducted in collaboration with China-based Biomics Biotechnologies Co. Ltd, the companies have reached agreement to proceed to the next stage which is designed to develop an RNAi therapeutic to the point of pre-clinical studies *in vivo*.

The overall aim of Benitec's HBV program is to develop a novel and effective therapeutic option for Hepatitis B, based on Benitec's DNA directed (dd)RNAi platform technology, to improve the lives and health outcomes for people with chronic HBV infection and also to reduce its spread. Current therapies have only limited inhibitory effects on viral gene expression and replication in the majority of chronically infected patients.

Under the terms of the new agreement, Benitec and Biomics will share the costs of the program, the ownership of the intellectual property and also commercialisation rights based on an agreed division of territories.

The first stage of the program commenced in 2010 and was successful in achieving its aim of identifying several target RNA sequences capable of inhibiting the replication of the virus. In that stage five thousand clones from the target viral gene were sequenced and over 500 potential RNA target sequences were identified. These RNA sequences were randomly distributed along the target gene. To identify the most effective RNA sequences, a laboratory model of HBV infection was used. One hundred of the 500 RNA sequences produced 50% or greater HBV gene knock down, 14 of which resulted in over 70% knock down.

This data provides a solid foundation for the second stage of the program under which the companies will carry out proof-of-principle studies *in vitro* and *in vivo* to optimise a pre-clinical ddRNAi-based therapeutic candidate. The second stage is expected to take around 18 months to complete.

"The application of Benitec's ddRNAi technology provides a unique route to directly targeting the activity of HBV genes with minimum off-target side effects. Identifying highly effective RNA sequences was the key to Benitec committing to the next stage of the program, and this was clearly achieved in stage 1," Dr Peter French, CEO of Benitec said.

Dr York Zhu, founder and President of Biomics Biotechnologies said, "Hepatitis B is a significant health issue in China, as well as globally. The stage 1 results are very exciting and we are delighted to be working with Benitec to help develop a potentially novel therapeutic for this disease."

Hepatitis B is a serious and common infectious disease of the liver, affecting millions of people throughout the world. More than 2,000 million people have been infected with HBV at some time in their lives and of these about 350 million remain chronically infected and become carriers of the virus. In the USA alone there are over 1.25 million people living with the consequences of chronic active HBV and over 60,000 new cases per year.

The severe pathological consequences of persistent HBV infections include the development of chronic hepatic insufficiency, cirrhosis, and liver cancer. In addition, HBV carriers can transmit the disease for many years.

"In stage 2 Benitec and Biomics will progress the program towards confirming the potential of ddRNAi to address the unmet clinical treatment needs for HBV-infected patients," Dr French concluded.

#### **For Further Information**

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#### **About Benitec ([www.benitec.com](http://www.benitec.com))**

Benitec holds a dominant position in expressed RNA interference (RNAi)-based human therapeutics, with a transformational platform technology supported by a robust and extensive intellectual property portfolio. Benitec is leveraging this platform to develop and build a pipeline of expressed RNAi therapeutics focusing on treatment and alleviation of cancer and infectious disease. With strong global partnerships and committed scientific and clinical investigators, Benitec Ltd aims to deliver a range of novel RNAi-based therapeutics to the clinic in partnership with the pharmaceutical industry.

#### **About Biomics Biotechnologies ([www.biomics.cn](http://www.biomics.cn))**

Biomics Biotechnologies Co. Ltd. is a biopharmaceutical company focusing on R&D of RNAi therapeutic technology based in Nantong, China. Biomics Biotech owns an integrated proprietary technical platform of siRNA screening, chemical modification and target tissue delivery. A number of siRNA therapeutics, such as for Age-related Macular Degeneration (AMD) and Hepatoma, are in the process of pre-clinical study.