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Benitec Provides Update on BB-401 Cancer Treatment Program

SYDNEY and HAYWARD, Calif., Dec. 21, 2018 /PRNewswire/ -- Benitec Biopharma (ASX: BLT, NADSAQ: BNTC) (the "Company"), a clinical-stage biotechnology company developing novel genetic medicines via the proprietary DNA-directed RNA interference (ddRNAi) platform combining RNA interference with gene therapy, today announced that BB-401, a gene silencing agent comprised of plasmid DNA which produces a 39-nucleotide antisense RNA with specificity against EGFR, is currently undergoing evaluation in a Phase II clinical trial onto which patients with recurrent or metastatic squamous cell carcinoma of the head and neck have been enrolled.

Patients enrolled in the Phase II clinical trial have been diagnosed with an advanced disease that is refractory to all available standard therapies and must have at least one malignant lesion that is amenable to direct injection with BB-401. An interim analysis was recently conducted to evaluate the objective response rate observed for the initial 12-patient cohort treated in Stage 1 of the Phase II study. Benitec's scientific and clinical teams continue to evaluate the data derived from the interim evaluation of the first cohort of patients treated in this Phase II study. However, based on the initial analysis, the objective response rate required to support continued patient enrollment into the Phase II study was not achieved.

Benitec's scientific and clinical teams will continue with patient follow-up for the patients treated in Stage 1 of the Phase II study and additional details will be disclosed following the completion of the comprehensive analyses of the clinical data derived from ongoing patient follow-up.

There are several critical points to note regarding the underlying nature of BB-401 as it relates to the other distinct investigational agents in the Benitec pipeline:

- At the molecular level, all of the investigational agents that are currently under development by Benitec are fundamentally different from BB-401. The proprietary investigational agents under development by Benitec employ ddRNAi which facilitates gene silencing via the production of short hairpin RNA-based molecules whereas BB-401 represents a modified antisense oligonucleotide.
- All of the investigational agents that are currently under development by Benitec function by a mechanism of action that is completely distinct from that of BB-401 which achieves gene-silencing via a mechanism described as post-transcriptional interference. The proprietary ddRNAi-based agents in the Benitec pipeline ultimately achieve gene-silencing via RNA interference driven by activation of the RNA-Induced Silencing Complex.
- All of the investigational agents that are currently under development by Benitec employ tissue-specific delivery vectors (e.g. AAV9) whereas BB-401 has no delivery vector and was delivered intratumorally as a "naked" plasmid.

About Benitec Biopharma Limited
Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) is a clinical-stage biotechnology company focused on the development of novel genetic medicines. The proprietary platform, called DNA-directed RNA interference, or ddRNAi, combines RNA interference, or RNAi, with gene therapy to create medicines that facilitate sustained silencing of disease-causing genes following a single administration. 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 oculopharyngeal muscular dystrophy (OPMD), squamous cell carcinoma of the head & neck (SCCHN), ophthalmolgic disorders such as wet age-related macular degeneration (AMD), and chronic hepatitis B. 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.

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 this ASX/Nasdaq announcement 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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