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Benitec Biopharma Launches its Phase 2 Oncology Study in Australia

SYDNEY, March 5, 2018 /PRNewswire/ -- Benitec Biopharma Limited (ASX: BLT; NASDAQ: BNTC; NASDAQ: BNTCW) ("Benitec" or "the Company"), a biotechnology company developing innovative therapeutics based on a combination of gene therapy and its patented gene-silencing technology named ddRNAi or 'expressed RNAi', today announced the start of its Phase 2 clinical study in Australia with BB-401 as a treatment for patients with head and neck squamous cell carcinoma (HNSCC).

The Phase 2 open label study has been designed to explore the safety, tolerability and efficacy of BB-401 following intratumoral injections into the lesions of patients with recurrent or metastatic HNSCC. The study will enrol up to 30 patients at 5-8 sites across Australia and Russia. The trial is registered on www.clinicaltrials.gov with the identifier: NCT03433027, where more details can be found.

Chief Executive Officer Greg West said, "I am delighted that we have received approval to commence the study in Australia. This represents an important milestone for us in the progression of BB-401 as a treatment option for patients with advanced head and neck cancer who have failed all other treatment modalities. We are on track to start screening patients shortly."

BB-401 is a recombinant DNA construct that produces an antisense RNA with specificity against Epidermal Growth Factor Receptor (EGFR). More than 90% of lesions from patients show significantly increased EGFR levels associated with HNSCC. The goal of this study is to inhibit the expression of EGFR in the treated lesions and thus control the progression of disease and increase patient survival.

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 Head and Neck Cancer:

Cancers that are known as head and neck cancers usually begin in the squamous cells that line the moist mucosal surfaces inside the head and neck, such as inside the mouth and the throat. In 2016, approximately 64,000 new cases of head and neck cancer were estimated to have been diagnosed in the U.S., resulting in more than 13,000 deaths.

Head and neck cancers are more than twice as common among men as they are among

women. Squamous cell carcinoma of the head and neck accounts for more than 90% of all head and neck cancers, and more than 50% of HNSCC patients present with Stage III or higher disease (locally advanced or metastatic), which has higher potential for progression and recurrence. The relative five-year survival rate for metastatic head and neck cancers is <38%, and can be as low as 4% for recurrent or metastatic Stage IV disease. Total drugs sales in the HNSCC markets in the seven major markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan) will increase from $386 million in 2014 to $1.53 billion in 2024, at a Compound Annual Growth Rate (CAGR) of 14.8%. Reference: GlobalData Report (February 2016): Head and Neck Squamous Cell Carcinoma – Opportunity Analysis and Forecast to 2024

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 OPMD, head & neck squamous cell carcinoma, retinal based diseases such as wet age-related macular degeneration, and hepatitis B.

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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