

# **ASX/NASDAQ ANNOUNCEMENT**

# Benitec Biopharma receives Russian Regulatory Approval for Oncology Study

**Sydney, Australia, 24 May 2018:** 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 provided an update on advancements of its Phase 2 clinical study in Australia with BB-401, as a treatment for patients with head and neck squamous cell carcinoma (HNSCC).

Benitec has now received Regulatory Approval from the Ministry of Health (MoH) of the Russian Federation allowing the conduct of the Phase 2 HNSCC study in Russia. The MoH approval follows the recently announced Australian Regulatory Approval from the Therapeutics Goods Administration (TGA).

Chief Executive Officer of Benitec, Greg West said, "We continue to make good progress in starting up the study in both Australia and Russia. We are now able to start treating head and neck cancer patients with this promising product and we look forward to the Russian clinical centres joining the study."

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 trial is registered on www.clinicaltrials.gov with the identifier: <a href="NCT03433027">NCT03433027</a>, where more details can be found. The study will enrol up to 30 patients at 5-8 sites across Australia and Russia.

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. The global incidence of HNSCC is expected to increase from approximately 119,000 cases in 2016 to over 136,000 cases in 2026. 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. For patients with recurrent of metastatic HNSCC the median overall survival is 7.8 months and the five year survival rate is 3.6%. Total drug sales in the HNSCC markets in the seven major markets (United States, France, Germany, Italy, Spain, United Kingdom and Japan) are expected to increase from \$579.4 million in 2016 to just over \$4.1 billion in 2026, at a Compound Annual Growth Rate (CAGR) of 21.6%. Reference: GlobalData Report (March 2018): Head and Neck Squamous Cell Carcinoma – Opportunity Analysis and Forecast to 2026.

#### 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 lifethreatening 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.