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Benitec Biopharma Enrolls First OPMD Subject into the Clinical Development Program

HAYWARD, Calif., Jan. 23, 2023 (GLOBE NEWSWIRE) -- Benitec Biopharma Inc. (NASDAQ: BNTC) ("Benitec" or "the Company"), a development-stage, gene therapy-focused, biotechnology company developing novel genetic medicines based on its proprietary DNA-directed RNA interference ("ddRNAi") platform, today announced the enrollment of the first oculopharyngeal muscular dystrophy (OPMD) patient into the OPMD natural history phase of the BB-301 clinical development program. The OPMD Natural History (NH) Study represents the 6-month pre-treatment observation period for each OPMD subject prior to the administration of BB-301 for the treatment of OPMD-related dysphagia. Upon the completion of 6-months of radiographic and clinical assessments required for the NH Study, participants will be eligible for enrollment into the BB-301 Phase 1b/2a treatment study in which BB-301 will be administered.

"Following the initiation of OPMD patient screening at the lead clinical site in the United States in the fourth quarter of 2022, the Principal Investigator of the OPMD NH Study reported high enrollment interest from potential study subjects," said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec Biopharma. "Today, we are excited to announce the enrollment of the first OPMD patient into the natural history phase of the BB-301 development program."

Dr. Banks continued, "The formal initiation of the OPMD NH Study represents a major milestone for Benitec, and the enrollment of the first patient supports our central clinical development goal of administering the first dose of BB-301 in 2023. We continue to work with regulators globally to open additional sites in geographies outside of the United States."

The OPMD NH Study will facilitate the characterization of OPMD patient disposition at baseline and assess subsequent rates of progression of dysphagia via the use of the following quantitative radiographic measures (i.e., videofluoroscopic swallowing studies or "VFSS"), with the VFSS outlined below collectively providing objective assessments of swallowing safety, swallowing efficiency, and the functional capacity of the specific pharyngeal constrictor muscles underlying the progression of dysphagia in OPMD patients:

- Total Pharyngeal Residue %$(C2\text{-}4)^2$
- Pharyngeal Area at Maximum Constriction (PhAMPC)
- Dynamic Imaging Grade of Swallowing Toxicity Scale (DIGEST)
- Vallecular Residue %$(C2\text{-}4)^2$, Pyriform Sinus Residue %$(C2\text{-}4)^2$, and Other Pharyngeal Residue %$(C2\text{-}4)^2$
- Normalized Residue Ratio Scale ($NRRS_V$, $NRRS_P$)

- Pharyngeal Construction Ratio (PCR)

The NH study will also employ clinical measures of global swallowing capacity and oropharyngeal dysphagia, along with two distinct patient-reported outcome instruments targeting the assessment of oropharyngeal dysphagia.

Upon the achievement of 6-months of follow-up in the NH Study, participants will be eligible for enrollment into the planned BB-301 Phase 1b/2a treatment study.

About Benitec Biopharma Inc.

Benitec Biopharma Inc. (“Benitec” or the “Company”) is a development-stage biotechnology company focused on the advancement of novel genetic medicines with headquarters in Hayward, California. 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. The Company is developing ddRNAi-based therapeutics for chronic and life-threatening human conditions including Oculopharyngeal Muscular Dystrophy (OPMD). A comprehensive overview of the Company can be found on Benitec’s website at www.benitec.com.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release include forward-looking statements, including statements regarding Benitec's plans to develop and commercialize its product candidates, the timing of the initiation and completion of pre-clinical 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, and other forward-looking statements.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA and other governmental authorities; the Company's ability to protect and enforce its patents and other intellectual property rights; the Company's dependence on its relationships with its collaboration partners and other third parties; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; the Company's ability to satisfy its capital needs through increasing its revenue and obtaining additional financing; given market conditions and other factors, including our capital structure; our ability to continue as a going concern; the length of time over which the Company expects its cash and cash equivalents to be sufficient to execute on its business plan; the impact of the current COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus, which may adversely impact the Company's business and pre-clinical and future

clinical trials; the impact of local, regional, and national and international economic conditions and events; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission. The Company disclaims any intent or obligation to update these forward-looking statements.

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