

# PureTech Health Announces Initiation of Phase 2b mTORC1 Inhibitors Study in Elderly Patients at Increased Risk of Respiratory Tract Infections

Study builds on efficacy and safety data from previous Phase 2 clinical studies, which suggest selective targeting of mTORC1

PureTech Health plc (LSE: PRTC), an advanced, clinical-stage biopharmaceutical company, today announced the initiation of a Phase 2b study of its mechanistic target of rapamycin complex 1 (mTORC1) program by its subsidiary, resTORbio. The study will evaluate the effectiveness of RTB101 alone or in combination with RAD001 in reducing the incidence of respiratory tract infections (RTIs) in elderly patients at increased risk of morbidity and mortality related to RTIs. Low doses of RTB101 alone or in combination with RAD001 have previously been shown to target mTORC1 selectively.

"We are pleased to announce the initiation of this study, which marks an important milestone in our effort to develop a new approach to treat aging-related diseases and conditions, including respiratory tract infections," said Chen Schor, PureTech Health Senior Executive and Chief Executive Officer of resTORbio. "Previous clinical studies by our partner Novartis have demonstrated the immune-enhancing potential of mTORC1 inhibitors in elderly populations. We look forward to building on this research and further evaluating our mTORC1 program for multiple indications, including immunosenescence—related conditions."

Immunosenescence, the age-dependent decline in immune function, is associated with a decreased ability to fight infections such as respiratory tract infections in the elderly. In the U.S., RTIs are the fourth leading cause of death in people over the age of 85; specifically, respiratory viruses, for which there are currently no effective treatments, cause the majority of community-acquired pneumonias in this population. Patients over the age of 65 with underlying risk factors including asthma, chronic obstructive pulmonary disease (COPD), type 2 diabetes mellitus (T2DM), congestive heart failure (CHF), and smoking are also at increased risk of RTI-related morbidity and mortality.

"Respiratory tract infections are more severe and result in more frequent emergency room visits and hospitalizations in the elderly as compared to younger adults" said Joan Mannick, M.D., Chief Medical Officer of resTORbio and former clinical lead of the mTORC1 program at Novartis. "By strengthening the immune system with our mTORC1 program in at-risk elderly populations, we could potentially decrease the burden of infectious diseases in the elderly, which would lead to decreased healthcare resource utilization globally and significantly improve the quality of life of the elderly."

The Phase 2b study builds on two successful Phase 2a studies conducted by Novartis that assessed the immune-enhancing potential of these mTORC1 inhibitors in hundreds of elderly patients. The unpublished results from one of those studies, which form the foundation for further clinical development of RTB101 alone or in combination with RAD001 for immunosenescence and other aging-related diseases, will be detailed in an upcoming peer-reviewed publication.

The 24-week multicentre, double-blinded, placebo-controlled dose range finding study will assess the effects of multiple doses of RTB101 alone or in combination with RAD001 on the incidence of RTI in elderly subjects at increased risk of RTI-related morbidity and mortality. The primary objective of the study is to evaluate the dose-response relationship of two different doses of RTB101 alone and of RTB101 in combination with RAD001, as measured by the percent of subjects experiencing one or more RTIs as compared to placebo. Study results are anticipated in the second half of 2018.



#### **About mTOR**

Mechanistic target of rapamycin (mTOR) is a protein serine/threonine kinase that regulates multiple cell functions, including cell growth and metabolism, via two complexes: TORC1 and TORC2. TORC1 inhibition has been found to have many beneficial effects on aging, while TORC2 inhibition has been associated with adverse events including hyperglycaemia and hypercholesterolemia. The mTORC1 inhibitors being developed by resTORbio potentially result in selective inhibition of mTORC1 and may therefore have therapeutic potential to ameliorate multiple aging-related conditions with a favourable safety profile.

#### About resTORbio

resTORbio, Inc., a subsidiary of PureTech Health (LSE: PRTC; www.puretechhealth.com), is developing medicines to treat aging-related diseases and conditions. resTORbio's lead program is targeting the mechanistic target of rapamycin complex 1 (mTORC1) pathway to treat aging-related diseases and conditions with an initial focus on conditions caused by immunosenescence, the decline in immune function due to aging. resTORbio's lead program is built upon two Phase 2 clinical studies demonstrating promising safety and efficacy results in almost 500 hundred elderly subjects. resTORbio is pursuing a pragmatic clinical development plan addressing areas of key unmet medical need in the aging population.

#### **About PureTech Health**

PureTech Health (PureTech Health plc, PRTC.L) is an advanced, clinical-stage biopharmaceutical company developing novel medicines that modulate the adaptive human systems. PureTech's therapies target the dysfunctions in the immune, nervous, and gastro-intestinal systems by addressing the underlying pathophysiology of disease from a systems perspective rather than through a single receptor or pathway. The Company is advancing a rich pipeline that includes multiple human proof-of-concept studies and pivotal or registration studies expected to read out over the next 12-18 months. PureTech Health's growing research and development pipeline has been developed in collaboration with some of the world's leading scientific experts, who along with PureTech's experienced team and a stellar Board identify, analyse and advance very selectively the opportunities the Company believes hold the most promise for patients. This experienced and engaged team places PureTech Health at the forefront of ground-breaking science and technological innovation and leads the Company between and beyond existing disciplines. For more information, visit <a href="https://www.puretechhealth.com">www.puretechhealth.com</a> or connect with us on Twitter <a href="https://www.puretechhealth.com">@puretechh</a>.

### **Forward Looking Statement**

This press release contains statements that are or may be forward-looking statements, including statements that relate to the company's future prospects, developments and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks and uncertainties described in the risk factors included in the regulatory filings for PureTech Health plc. These forward-looking statements are based on assumptions regarding the present and future business strategies of the company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, neither the company nor any other party intends to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.



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