

## Rejuvenate Biomed, the NIHR Leicester BRC, and Wellcome Leap partner for Phase 2 Study in COPD-related sarcopenia

*The Phase 2 double-blind placebo-controlled clinical trial will evaluate the potential of RJx-01 to maintain muscle integrity in older persons with severe acute exacerbation of COPD*

*Rejuvenate Biomed anticipates commencing patient enrollment first half 2025*

DIEPENBEEK, Belgium, LEICESTER, England, and LOS ANGELES, USA, (October 28, 2024) - [Rejuvenate Biomed](#), the University of Leicester, [the National Institute for Health and Care Research \(NIHR\)](#) Leicester Biomedical Research Centre (BRC), and Wellcome Leap Inc. announced today that they have entered into an agreement to execute a Phase 2 clinical trial in patients with chronic obstructive pulmonary disease (COPD)-related sarcopenia.

COPD is the third largest cause of mortality worldwide<sup>1</sup>, and one of the major long-term conditions leading to disability. While COPD is primarily a lung disease, it has significant systemic effects that extend beyond the respiratory system, including impaired skeletal muscle mass and function, also referred to as sarcopenia. Often, people living with COPD end up in hospital with a flare-up of their condition, where there is further worsening of their physical function. These systemic manifestations of sarcopenia for which therapeutic interventions are lacking, are important predictors of mortality, morbidity and healthcare utilization independent of the severity of lung function impairment. As such, there is a strong rationale for the development of pharmaceutical agents that target skeletal muscle dysfunction in patients with COPD to improve overall patient outcomes.

In a Phase 1b trial, Rejuvenate Biomed's novel combination drug RJx-01 demonstrated great potential as an oral treatment for sarcopenia, showing meaningful improvements in muscle strength, function, and fatigue resistance in people with disuse-induced muscle weakness.

The new study, a double-blind placebo-controlled trial, will evaluate the safety and tolerability of RJx-01 in 130 older individuals following hospitalization with severe acute exacerbation of COPD. In addition, the effects of RJx-01 on physical function, muscle strength and fatigability will be assessed.

The clinical study is enabled by a multimillion dollar award from [Wellcome Leap's](#) Dynamic Resilience program (co-funded by Temasek Trust). The [Dynamic Resilience program](#) aims to improve biological resilience in clinically vulnerable people at-risk of adverse outcomes after a stressor event, by identifying resilience biomarkers and mechanisms and facilitating proof-of-concept studies and clinical trials of potential preventative interventions. This study will be led by Dr. Neil Greening and Dr. Hamish McCauley from the NIHR Leicester BRC at University Hospitals of Leicester NHS Trust.

"We are grateful for the support of NIHR Leicester BRC and Wellcome Leap as we explore the potential of RJx-01 as a treatment for patients living with COPD suffering from muscle weakness," said Dr. Ann Beliën, Founder and Chief Executive Officer of Rejuvenate Biomed. "Positive results from our recent Phase 1b study underscore RJx-01's potential to prevent and treat sarcopenia induced by other

conditions, and improve patients' quality of life. We look forward to initiating this Phase 2 study in COPD patients."

Dr Neil Greening, Associate Professor at the University of Leicester said "Muscle wastage is a significant burden for many of our COPD patients and it can impact on their ability to recover, particularly when they are in hospital and experiencing exacerbations. Finding ways to maintain muscle function is increasingly important, which is why we're delighted to be working with Rejuvenate Biomed and on this world-first study, enabled by Wellcome Leap."

Prof Lynne Cox, Program Director of Wellcome Leap's Dynamic Resilience program added: "We urgently need treatments that can help prevent muscle wastage and frailty progression when people are hospitalized with acute illness, to enable them to return home and live safely and independently. We are therefore excited to support the globally excellent clinical, academic and industry teams in this study which addresses that major unmet need."

1. Institute for Health Metrics and Evaluation. Global Burden of Disease Study 2019 (GBD 2019) results. Seattle, WA: Institute for Health Metrics and Evaluation, 2019

### **About Rejuvenate Biomed**

Rejuvenate Biomed is an AI-powered, clinical-stage biotech company decoding the biology of aging to develop safe, synergistic combination therapeutics that holistically address the root causes of age-related diseases. By targeting multiple disease pathways simultaneously, the company aims to provide more effective treatments that can alter the course of disease. Utilizing two clinically validated proprietary drug discovery platforms, the AI-enabled *in silico* CombinAge™ and *in vivo* CelegAge™, Rejuvenate Biomed has generated a robust pipeline of five unique combination drugs targeting different age-related diseases, including neuromuscular, musculoskeletal, metabolic, cardiovascular, nephrological, and neurodegenerative indications. Its lead Phase 2-ready asset, RJx-01, has already demonstrated significant potential in treating sarcopenia. The company's disease agnostic drug discovery platforms continue to provide insight into future therapeutics, driving pipeline growth and potential partnerships. Rejuvenate Biomed is dedicated to promoting healthy aging.

For more information, please visit <https://www.rejuvenatebiomed.com/en>

### **About the NIHR Leicester Biomedical Research Centre**

The National Institute for Health and Care Research (NIHR) Leicester Biomedical Research Centre (BRC) is part of the NIHR and hosted by the University Hospitals of Leicester NHS Trust, in partnership with the University of Leicester, Loughborough University and the University Hospitals of Northamptonshire National Health Service Group. The NIHR Leicester BRC undertakes translational clinical research in priority areas of high disease burden and clinical need.

### **About Wellcome Leap**

Wellcome Leap builds and executes bold, unconventional programs, funded at scale. Programs that aim to deliver breakthroughs in human health over 5 – 10 years. Founded in 2020, Leap programs

target complex human health challenges with the goal of achieving breakthrough scientific and technological solutions. Operating at the intersection of life sciences and engineering, Leap programs require best-in-class, multi-disciplinary, global teams assembled from universities, companies, and nonprofits working together to solve problems that they cannot solve alone.

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