

Rejuvenate Biomed announces positive results from Phase 1b clinical trial with RJx-01 in sarcopenia

- *RJx-01 met all primary and secondary endpoints in the placebo-controlled Phase 1b in disuse-induced muscle atrophy*

Diepenbeek, Belgium, October 4, 2023 – Rejuvenate Biomed NV (“Rejuvenate Biomed”), a clinical-stage company dedicated to advancing therapeutics to delay the onset of age-related diseases, today announced the successful completion of a 6-week clinical proof-of-mechanism study with lead candidate RJx-01. RJx-01, a novel combination drug comprising galantamine and metformin, demonstrated positive results in 42 elderly male subjects with disuse-induced muscle atrophy.

In this successful Phase 1b trial, RJx-01 met all primary and secondary endpoints. RJx-01 was generally safe and well tolerated with no reported treatment-related serious or severe adverse events. The proprietary and innovative RJx-01 formulation exhibited excellent bioavailability.

Results evaluating the impact of RJx-01 on exploratory pharmacodynamic parameters, including blood and muscle-related biomarkers, along with clinical assessments of muscle mass and strength, are anticipated later this year. Rejuvenate Biomed is gearing up to initiate a Phase 2 program focused on RJx-01 in the treatment of sarcopenia in 2024.

Dr. Silke Huettner, Chief Medical Officer of Rejuvenate Biomed, said: *“This proof-of-mechanism study has confirmed the excellent pharmacokinetics, as well as the safety and tolerability profile of RJx-01. As we eagerly anticipate the forthcoming results on the exploratory endpoints, we are confident to embark on a Phase 2 program dedicated to the treatment of sarcopenia in 2024. The advancement of our lead program is paving the way for the expansion of the broader pipeline via our drug discovery platforms.”*

Dr. Ann Beliën, Founder and Chief Executive Officer of Rejuvenate Biomed, added: *“We are thrilled to unveil compelling initial data from the Phase 1b study of RJx-01, confirming the power of our drug discovery platforms. This represents a pivotal milestone in our mission to keep people healthy for life, starting with addressing muscle aging in sarcopenic patients.”*

Sarcopenia, a musculoskeletal disease characterized by the progressive loss of skeletal muscle strength and mass, poses a significant health challenge. The disease manifests chronically with age or as an acute condition induced by muscle disuse, for example following immobilization due to a stay in hospital. Chronic sarcopenia affects up to 22% of 65-year-olds and 50% of 80-year-olds, with no currently approved drug treatments.

In this Phase 1b trial, a randomized, double-blind, placebo-controlled study, 42 healthy men aged 65 to 75 volunteered to have one leg immobilized in a cast for two weeks, thereby inducing mild acute sarcopenia. Subsequently, they were closely monitored during the immobilization phase and for an additional four weeks post-cast removal in the recovery phase. Throughout the entire six-week treatment duration, half of the participants (21) received RJx-01, while the other half (21) received a placebo. Following this period, all volunteers underwent a personalized muscle strength rehabilitation program.

This significant clinical trial builds on preclinical proof-of-concept data generated from two mouse models. These promising results were recently published in *JCI Insight*, titled "[A combination of metformin and galantamine exhibits synergistic benefits in the treatment of sarcopenia](#)".

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About Rejuvenate Biomed

Established in 2017, Rejuvenate Biomed is a privately-held, clinical-stage platform and pipeline company, committed to redefine the aging process. Envisioning a future where people stay healthy for life, the Company is dedicated to the discovery and development of innovative combination drugs that can safely delay the onset of various age-related diseases. RJx-01 is ready for a Phase 2b clinical trial in sarcopenia, a musculoskeletal disease. Rejuvenate Biomed has developed two proprietary drug discovery platforms, *in silico* CombinAge™ and *in vivo* CelegAge™, to efficiently screen molecule libraries across a wide spectrum of age-related pathways. These molecules are developed into unique combination drugs with the potential to influence the underlying molecular mechanisms of aging. The Company is headquartered on the Health Campus Limburg in Belgium. To learn more about Rejuvenate Biomed's approach, click [here](#).

About the RJx-01-101 study

RJx-01-101 is a randomized, double-blind, placebo-controlled clinical trial where 42 healthy 65 to 75-year-old male subjects were immobilized for 2 weeks and treated with RJx-01 for 6 weeks. RJx-01 is an orally administered proprietary combination drug, identified by Rejuvenate Biomed's drug discovery platforms. This lead candidate is in development for sarcopenia and other age-related diseases. The primary objective of the Phase 1 study was to evaluate the safety and tolerability of daily administration of RJx-01's new formulation. The secondary objective focuses on the RJx-01's pharmacokinetics. The study also explored the impact of RJx-01 on pharmacodynamic parameters, including blood and muscle-related biomarkers, as well as clinical assessments of muscle mass and strength. Following the trial, all volunteers underwent a personalized rehabilitation program.