

Rejuvenate Biomed’s clinical trial demonstrates the therapeutic potential of RJx-01 in sarcopenia

Cutting-edge therapy shows meaningful improvements in muscle strength, function and fatigue resistance, offering hope for millions suffering from sarcopenia

Diepenbeek, Belgium, February 21st, 2024 – Rejuvenate Biomed NV (“Rejuvenate Biomed”), a pioneering clinical-stage platform and pipeline company committed to enhancing lifelong health through innovative therapeutics, today announces breakthrough functional outcome results from its Phase 1b trial of lead candidate RJx-01 for the treatment of sarcopenia.

Sarcopenia, a condition affecting up to 22% of 65-year-olds and 50% of 80-year-olds, is characterized by the progressive loss of muscle strength and physical performance. This decline not only impacts the quality of life but also elevates the risk of falls, disability, and mortality, particularly among the older population.

RJx-01 is a proprietary combination drug that was identified by the Company’s in-house drug discovery platform and has shown to have beneficial effects on various preclinical models of sarcopenia [1]. The recent exploratory clinical trial results, which follow earlier confirmation of safety and tolerability and pharmacokinetics [2], highlight the potential of RJx-01 in addressing the unmet need for effective sarcopenia treatments.

The key findings of the Phase 1b trial with RJx-01 reveal promising functional outcomes:

1. **Improved strength:** Participants with disuse-induced sarcopenia treated with RJx-01 exhibited a promising improvement in muscle strength recovery compared to the placebo group. This beneficial effect, assessed through isometric dynamometry, underscores the ability of RJx-01 to promote muscle strength improvement, an outcome that would support the daily activities of sarcopenia patients.
2. **Improved muscle function:** Treatment with RJx-01 led to an important improvement of leg acceleration, assessed through isokinetic dynamometry. The ability to accelerate the limb rapidly is important for functional movement in daily activities and is pivotal in mitigating fall risks – a critical consideration for sarcopenia patients.
3. **Improved fatigue resistance:** Neuromuscular fatigue was assessed by monitoring muscle parameters during a series of leg exercises. Participants receiving RJx-01 showed a reduced propensity for fatigue indicating that RJx-01 can promote physical activities such as walking, a performance improvement that is important for sarcopenia patients.

Dr. Ann Beliën, Founder and Chief Executive Officer of Rejuvenate Biomed, expressed her enthusiasm, stating: *“Today marks a pivotal moment in our journey to address age-related diseases, most notably sarcopenia – a condition affecting up to 1 in 5 individuals over 65 years. The impact demonstrated by RJx-01 offers great potential to make a substantial difference for individuals with sarcopenia or muscle strength loss due to other underlying factors. We eagerly anticipate advancing our Phase 2 program later this year, aiming to substantiate RJx-01’s therapeutic potential in addressing sarcopenia and osteoporosis.”*

Prof. Dr. Jean-Yves Reginster, Chair of Rejuvenate Biomed’s Clinical Advisory Board, added: *“These compelling data confirm RJx-01’s promise to improve physical performance and muscle strength. With aging populations, it is inevitable that the number of people living with long-term health conditions will rise, challenging ones functional abilities and overall physical performance. Thus, it is crucial that companies like Rejuvenate Biomed work towards the goal of treating and even preventing the development of age-related diseases such as sarcopenia.”*

Prof. Dr. Roger Fielding, Clinical Advisory Board member of Rejuvenate Biomed, echoed his resounding endorsement: “The number of people living with muscle-related conditions is increasing, emphasizing the urgent need for viable solutions to improve the age-related decline in muscle performance. The new data announced today by Rejuvenate Biomed regarding RJx-01 are very promising for patients with sarcopenia, as well as for those experiencing a loss of muscle function due to other causes.”

Rejuvenate Biomed will commence a Phase 2 study evaluating RJx-01’s effect on sarcopenia and osteoporosis, as these two diseases often co-exist, so frequently that ‘osteosarcopenia’ has recently been described in medical literature as a distinct syndrome.

Additionally, the Company is actively exploring partnership opportunities to investigate RJx-01 in combination with GLP-1 drugs, that are marketed for obesity and diabetes type 2.

The positive outcomes from the Phase 1b trial validate the predictive power of Rejuvenate Biomed’s proprietary drug discovery platforms CombinAge™ and CelegAge™, which efficiently screen small molecules to identify promising therapeutics targeting age-related pathways. Rejuvenate Biomed intends to make these platforms available to third parties through strategic partnerships or licensing agreements.

1. Tezze C, et al. *JCI Insight* 2023; 8(15): e168787. <https://doi.org/10.1172/jci.insight.168787>
2. <https://www.rejuvenatebiomed.com/en/news/positive-results-phase-1b-trial-in-sarcopenia>

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About Rejuvenate Biomed

Rejuvenate Biomed is a clinical-stage platform and pipeline company dedicated to redefining the aging process. The Company leverages validated platform technology to develop innovative therapeutics targeting the root causes of age-related diseases. With two distinct drug discovery platforms – AI-enabled *in silico* CombinAge™ and *in vivo* CelegAge™ – Rejuvenate Biomed has demonstrated the predictive power of this approach, resulting in a pipeline of five unique combination drugs targeting various age-related diseases, including neuromuscular, musculoskeletal, metabolic, cardiovascular, nephrological, and neurodegenerative indications. Headquartered in Belgium, Rejuvenate Biomed is committed to promoting healthy aging. Visit <https://www.rejuvenatebiomed.com/en> for more information.

About the RJx-01-101 study

RJx-01-101 is a randomized, double-blind, placebo-controlled clinical trial that successfully met primary and secondary endpoints, demonstrating positive clinical outcome data. Involving 42 healthy male subjects aged 65 to 75 with disuse-induced sarcopenia, the trial confirmed the safety, tolerability, and bioavailability of RJx-01 after 6 weeks of treatment. The Phase 1b study explored RJx-01’s impact on various pharmacodynamic parameters, paving the way for further investigations in sarcopenia and related conditions. Following the trial, participants underwent a personalized rehabilitation program.