

## **Elevara Medicines Doses First Patient in Phase 2b START-SYNERGY Trial of ELV001 in Rheumatoid Arthritis Patients with Incomplete Response to TNFi**

- ***ELV001 aiming to disrupt the treatment paradigm for patients with incomplete response to standard of care (methotrexate + TNF inhibitors)***
- ***Phase 2b trial enrolling approximately 180 patients across nine countries***
- ***Primary endpoint: change in DAS28-CRP at week 12, a validated measure of rheumatoid arthritis disease activity***
- ***Building on earlier clinical studies demonstrating ELV001 is well tolerated and showing early signals of clinical activity***

**London, UK – 16 March 2026** – Elevara Medicines (“Elevara”), a clinical-stage biotech developing therapies for rheumatoid arthritis (RA) and chronic inflammatory diseases, today announced dosing of the first patient in the Phase 2b START-SYNERGY clinical trial evaluating ELV001, a novel oral CDK4/6 inhibitor, in patients with rheumatoid arthritis (RA) who have an incomplete response to methotrexate (MTX) and tumour necrosis factor (TNF) inhibitors.

START-SYNERGY is a randomised, placebo-controlled Phase 2b trial designed to enrol approximately 180 patients across nine countries, including the United States, South Africa, Serbia, Poland, Czech Republic, Spain, the Netherlands, Bulgaria, and Hungary. Patient recruitment is currently underway across participating sites in North America and South Africa, with additional sites expected to open across Europe later this year.

START-SYNERGY builds on earlier clinical studies demonstrating that ELV001 was well tolerated in patients with RA and showed early signals of clinical activity.

The study is evaluating ELV001 as an oral add-on therapy to standard of care MTX and TNF inhibitors in patients who continue to experience active disease despite current treatment. The primary endpoint is change in DAS28-CRP at week 12, a validated measure of RA disease activity that assesses measures including tender joint count and levels of C-reactive protein in the blood.

According to the World Health Organization, RA affects more than 18 million people worldwide<sup>1</sup> and remains a leading cause of disability. Biologic and targeted therapies have transformed the treatment landscape in RA, but many patients treated with standard of care therapies do not achieve sustained remission. Treatment strategies often involve cycling between therapies that target related immune pathways.

***“Dosing the first patient in START-SYNERGY marks an important milestone for Elevara and the clinical development of ELV001, since we raised our \$70m Series A in October 2025,” said Emma Tinsley, Chief Executive Officer of Elevara Medicines. “Despite significant***

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<sup>1</sup> World Health Organization (WHO) fact sheet on rheumatoid arthritis 28 June 2023 <https://www.who.int/news-room/fact-sheets/detail/rheumatoid-arthritis> and GBD 2019: Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019 <https://vizhub.healthdata.org/gbd-results/>.

*therapeutic advances, many patients continue to experience active disease even after treatment with multiple immune-targeted therapies. ELV001 was developed to target mechanisms that may contribute to persistent synovial pathology and to be used alongside existing treatments. We believe this study will provide important insights into whether targeting these pathways can improve outcomes for RA patients.”*

There is now growing interest in the role of tissue-resident stromal cells in sustaining chronic inflammatory diseases. Increasing evidence suggests that RA may be sustained not only by immune cells but also by pathological stromal cells within the joint, particularly synovial fibroblasts that drive persistent inflammation and joint destruction.

Data shows that ELV001 selectively inhibits cyclin-dependent kinases 4 and 6 (CDK4/6), signalling pathways that regulate synovial fibroblast proliferation and inflammatory activity. By targeting these mechanisms, the therapy is designed to address an orthogonal component of disease biology, potentially leading to synergistic efficacy in combination with immunosuppressive therapies.

*“Even with modern biologic therapies, a substantial proportion of patients continue to have active disease,” said **Professor Dominique Baeten, Chief Medical Officer of Elevara Medicines.** “Synovial fibroblasts are increasingly recognised as active contributors to disease persistence in RA. START-SYNERGY will evaluate whether ELV001 can provide a new therapeutic approach for patients who have not achieved adequate response to existing treatments.”*

More information about the study is available at: <https://clinicaltrials.gov/study/NCT07409103>.

**-Ends-**

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**Notes to Editors**

**Elevara Medicines**

Elevara is a clinical stage company developing new therapeutics to treat rheumatoid arthritis (RA) and other chronic inflammatory conditions. The Company's lead program, ELV001, is a potent, selective, and well-differentiated first-in-class oral CDK4/6 inhibitor which is being tested in a global Phase 2b START-SYNERGY trial, currently recruiting in the US and South Africa, with sites in Europe opening in 2026. The ELV001 program is being positioned as an add-on oral therapy for RA patients with an incomplete response to a tumour necrosis factor (TNF) inhibitor, preventing cycling between multiple immunosuppressive therapies. The



company was co-founded by Weatherden (a UK based clinical advisory group) and Monograph Capital. The Company raised \$70m in a Series A in September 2025 and its investors are Sofinnova Partners, Forbion, and Monograph Capital. For more information, visit [www.elevara.com](http://www.elevara.com).

### **About ELV001**

ELV001 is an investigational oral inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6) designed for use in chronic inflammatory diseases. CDK4/6 signalling regulates cell-cycle progression and inflammatory signalling in synovial fibroblasts, cells that play an important role in joint inflammation and tissue damage in RA. By targeting these pathways, ELV001 is being developed as a potential therapy to complement existing immune-targeted treatments.

### **About the START-SYNERGY Trial**

START-SYNERGY is a Phase 2b randomised, placebo-controlled clinical trial evaluating ELV001 in patients with RA who have an incomplete response to methotrexate and TNF inhibitor therapy. The study is designed to enrol approximately 180 patients across nine countries. The primary endpoint is change in DAS28-CRP at week 12.

More information about the study is available at: [www.clinicaltrials.gov/study/NCT07409103](http://www.clinicaltrials.gov/study/NCT07409103).