Solfarcos nears completion of Phase 2a clinical trial for its innovative methotrexate nanotechnology for treatment of Rheumatoid Arthritis

FBL-MTX — Solfarcos' folate-targeted liposomal methotrexate — shows promising clinical Phase 2a progress that may reshape rheumatoid arthritis management and support future expansion into additional chronic inflammatory and oncological conditions

Key Phase 2a clinical study highlights

- Designed to integrate an innovative, cost-efficient technology that enhances treatment accessibility and patient well-being;
- Strong indications of reduced acute adverse effects on administration day, improving patient comfort;
- Improved tolerability profile, supporting better adherence and reducing indirect treatment costs;
- Potential for lower dosing frequency (monthly or semi-monthly instead of weekly);
- 7 clinical centers participating in the study in Portugal;
- FBL-MTX is estimated to have the potential of capturing ~1.3% of the RA drug market in the first commercial year (10% of new oral MTX patients + 10% of new SC MTX patients).

The aforementioned results will pave the way to extend the effective use of methotrexate, helping patients remain on a well-established therapy longer and postponing or avoiding transition to significantly more expensive biological treatments. Also, since the proprietary technology developed by Solfarcos can potentially be used for several conditions, the company also expects to broaden the scope of its partnerships moving forward.

Braga, Portugal — [INSERT DATE] — Solfarcos, a Portuguese biotechnology company inspired by nature and driven by the transformative potential of peptides, announces significant progress in the clinical development of FBL-MTX, its innovative folate-targeted liposomal methotrexate formulation for rheumatoid arthritis (RA). The therapy addresses a well-recognized challenge in chronic disease management: maintaining the efficacy and accessibility of methotrexate while improving tolerability, reducing treatment burden, and supporting long-term adherence and efficacy. As it gets ready to enter the next phase, the company expects to obtain market approval in 2033 and be the golden standard for rheumatoid arthritis treatment by 2038.

According to Artur Cavaco Paulo, Solfarcos' CEO and CSO, "for the past seventeen years, FBL-MTX has embodied our vision of combining scientific

excellence, technological innovation, and a clear commitment to improving the lives of people suffering from this chronic disease. We firmly believe that we are closer than ever to delivering a methotrexate-based therapy that is effective, accessible, and better aligned with patients' daily realities."

"This achievement has been made possible by a wide network of exceptional partners — researchers, clinicians, regulatory experts, manufacturers, and the volunteers (healthy subjects and RA patients) who participated in our studies. We are deeply grateful for their dedication and trust. Looking ahead, we remain committed to unlocking the full potential of this technology, not only in rheumatoid arthritis but across other chronic inflammatory conditions and selected oncological indications where improved therapeutic options are urgently needed."

RA affects more than 20 million people worldwide and contributes to disability, reduced quality of life, and escalating healthcare costs. Although methotrexate remains the anchor drug in RA, its low bioavailability, tolerability issues and weekly dosing schedule frequently impair adherence and force early transition to higher-cost biologics. Many patients discontinue methotrexate despite its proven value, primarily due to side effects that disrupt daily routines. FBL-MTX was developed precisely to extend the effective use of methotrexate for these chronic patients.

Solfarcos' proprietary technology uses folate anchored into the liposomes by peptides to enhance delivery of methotrexate to inflammatory immune cells. This approach improves bioavailability, protects the drug after administration, reduces off-target exposure, and may allow for less frequent dosing — once or twice per month instead of weekly. By improving tolerability and patient comfort, FBL-MTX aims to support better therapy adherence and reduce indirect treatment costs while delaying or avoiding the escalation to significantly more expensive therapies. The formulation also benefits from a simplified nanoparticle production method at the core of Solfarcos' platform technologies, that allow for the creation of liposomes with over 4 years of stability.

A sound and proven track of research with broader possible uses

FBL-MTX builds on 17 years of scientific research and more than €10 million in European R&D funding, progressing from fundamental discovery to a First-in-Human Phase 1 study and into the current Phase 2a proof-of-concept trial. Now close to completion, its Last Patient In status was achieved in mid-January and Last Patient Last Visit is expected by July 2026. Following full data analysis, Solfarcos will conduct the required non-clinical long-term safety studies needed for chronic therapies before initiating Phase 2b/3 program.

Beyond rheumatoid arthritis, **the underlying technology may enable broader therapeutic applications.** Low-dose methotrexate is widely used in autoimmune-mediated inflammatory diseases such as psoriasis, and in oncology in higher-dose regimens. Improved tolerability, targeted delivery and enhanced efficiency open opportunities for Solfarcos to explore future chronic inflammatory indications and selected oncology settings, including potential novel low-dose MTX applications for cancer remission strategies.

FBL-MTX in numbers

- 17 years of research
- 13 million-euro investment
- 28 rheumatoid arthritis patients treated with FBL-MTX
- 2 patented technologies
- Impact on over 20 million patients worldwide
- 40x lower dose of methotrexate per month
- Increase from 3 to 10+ days of methotrexate circulating in the blood

About Solfarcos

Solfarcos is a biotechnology company inspired by nature and driven by the transformative power of peptides. Focused on pharmaceutical and cosmetic applications, the company develops proprietary peptide- and protein-based bioactives and nanotechnology solutions that enhance health, well-being and sustainability. Its innovations leverage peptide-anchored targeted delivery systems and streamlined nanoparticle production methods to create cost-efficient therapeutic and dermocosmetic advances.

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