

ROS Therapeutics receives regulatory green light to initiate its first clinical trial with Trexior™ in patients with rheumatoid arthritis.

July 01, 2021

ROS Therapeutics announces regulatory green light to proceed into a pilot clinical study (protocol ROS-MTXREF-101) to investigate the relative bioavailability of Trexior™, a modified release methotrexate formulation, in comparison to oral and subcutaneous reference methotrexate formulations.

"I am happy to be in a position to test our proprietary product, Trexior, in patients with rheumatoid arthritis. ROS Therapeutics has now become a clinical stage company. I see this as a major achievement for a small company like ours. This could not have been achieved without our solid collaborations with excellent service providers", says Hanne Damgaard Jensen, CEO of ROS Therapeutics.

Smerud Medical Research International AS (Norway) supported by Clinical Trial Consultants AB (CTC) (Sweden) with use of their phase I unit in Uppsala as the clinical test site, provides a unique full service clinical CRO set-up to ensure smooth planning and execution of the clinical study.

Solural Pharma, a Danish Small-to-Medium sized Enterprise with strong expertise in formulation development and GMP manufacturing has developed, manufactured and provided documentation for the Trexior product to be tested in the study.

About Trexior™: Trexior is an innovative proprietary and potentially best-in-class orally delivered methotrexate therapy. Several of the shortcomings of existing methotrexate therapies, whether oral or injections, are sought to be overcome with Trexior.

About methotrexate: Methotrexate (MTX) is a cornerstone treatment for juvenile idiopathic arthritis (JIA), one of the most common childhood diseases, as well as for rheumatoid arthritis (RA), a common autoimmune inflammatory disease of adults. Since the early 90's, MTX has had a secure place as the anchor drug in the treatment of these diseases and has been shown to have a synergistic relationship with biological therapies.

About ROS Therapeutics: ROS Therapeutics ApS is a development stage pharmaceutical company, committed to optimizing the treatment experience with methotrexate and addressing unmet needs of children with JIA and RA and other autoimmune and chronic inflammatory conditions.

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