ROS Therapeutics receives regulatory green light for clinical trial amendment to initiate an additional number of patients with rheumatoid arthritis.

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ROS Therapeutics announces regulatory green light to proceed with an amendment to the 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.

"Based on the results of the main pilot clinical study completed last year, we have worked on improving the formulation of Trexior. We now obtained regulatory green light to test the optimised formulation of Trexior in patients with rheumatoid arthritis and we hope to be able to provide data from the study before the end of 2022", says Hanne Damgaard Jensen, CEO of ROS Therapeutics.

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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