Press release
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Cyxone receive ethical and regulatory approval from Georgia to conduct clinical Phase 2b study in RA

Cyxone (publ), a biotech company in autoimmune diseases, have received approvals from the Medical Product Agency (LEPL regulation Agency for Medical and Pharmaceutical Activities) and local Ethics Committees in Georgia to conduct a clinical Phase 2b study with its drug candidate Rabeximod, which is being developed as a treatment for rheumatoid arthritis (RA).

APPRAIS is a multicenter, randomised, double-blinded, placebo-controlled clinical study where patients with moderate to severe RA, who have previously been treated with methotrexate with inadequate response, will be treated with Rabeximod for 24 weeks. The aim of the study is to confirm the therapeutic efficacy of Rabeximod in this patient population, as well as to expand the safety data documentation.

“It is a pleasure to announce that ethical and regulatory approval has been obtained by the Medical and Pharmaceutical authorities in Georgia. After a slightly prolonged process we are glad to receive this confirmation which is a very important step in advancing the APPRAIS study. The Georgian authorities approved the study without any reservations. The approval from Georgia is the third study approval, also including Poland and Hungary, giving us confidence in the soundness of the protocol and the study design,” says Carl-Magnus Högerkorp, CEO, Cyxone.

Rabeximod is a well-tolerated, orally available Phase 2 candidate drug with a unique mechanism of action. Rabeximod selectively targets the inflammatory macrophage, a type of white blood cell which is the central orchestrator of the inflammatory process that causes tissue destruction and clinical symptoms in RA. Combined with the convenience of oral administration and a beneficial tolerability profile, this opens up for treatment in the early as well as later stages of the disease. It is believed to be particularly effective at onset and relapses of RA, with good potential to prevent joint destruction and progression of the disease.

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About Cyxone

Cyxone AB (publ) (Nasdaq First North Growth Market: CYXO) develops disease modifying therapies for diseases such as rheumatoid arthritis and multiple sclerosis. Rabeximod is a Phase 2 candidate drug being evaluated for the management of rheumatoid arthritis. T20K is a Phase 1 candidate drug for treatment of multiple sclerosis. Certified Adviser is FNCA Sweden AB. For more information, please visit www.cyxone.com