Press release

2019-11-12

SynAct receives approval from the Swedish Medical Product Agency and the Swedish Ethical Review Authority regarding the clinical Phase IIa study with AP1189

SynAct ("SynAct") announces that the company has received approval from the Swedish Medical Product Agency and the Swedish Ethical Review Authority to conduct the company's Phase IIa study with the drug candidate AP1189. SynAct also announces that an application for clinical trial has been filed to the Norwegian Medicines Agency and Norwegian National Committee for Medical and Health Research Ethics.

The Study is currently ongoing on clinical sites in Denmark following approval by the Danish Medicines Agency in June 2019. With the approval by the Swedish Medical Product Agency, patients can be included at Swedish sites as soon as the mandatory study initiations procedures has been completed. Dosing at Swedish sites can therefore be commenced in December 2019. Dosing in Norway will, pending approval, be initiated in early 2020.

The Phase IIa clinical trial entitled "A double-blind, multi-center, two-part, randomized, placebo-controlled study of the safety, tolerability, and efficacy of 4 weeks of treatment with AP1189 in early rheumatoid arthritis (RA) patients with active joint disease ", has been ongoing with active recruitment of patients since August 2019. Previous methotrexate naïve patients with active Rheumatoid Arthritis are randomized in the study, with a daily oral intake of AP1189 or placebo treatment, as an add-on to methotrexate therapy during a period of four weeks. Interim data from the from the first part of the study is planned to be reported by the end of Q1 2020. Results from the full study is planned to be reported in Q1 2021.

CEO Jeppe Øvlesen comments:
"Following the successful initiation of our phase II clinical study in active rheumatoid arthritis with AP1189 in Denmark, our next goal was to expand the study to the other Nordic countries. With the approval by the Swedish Medical Product Agency, we are now looking forward to working with dedicated rheumatological sites in Sweden on our new treatment concept for Rheumatoid Arthritis. To expand the study further within the Nordic countries we have filed a clinical trial application in Norway and expect to be able to initiate the study in Norway in the beginning of next year. We believe that the interest from the sites is associated to the fact that our project addresses a new concept for treatment of rheumatoid arthritis and, in a broader perspective, treatment of inflammatory and auto-immune diseases. The concept of Resolution therapy as applied with the AP1189 compound is seen as an attractive alternative to most current therapeutic approaches since the AP1189 compound strengthens the immune system's healing mechanisms, unlike most of today's drugs which inhibit the body's immune system."

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This information is such information that SynAct Pharma AB is obliged to publish in accordance with the EU Market Abuse Regulation. The information was submitted, through the agency of the above contact person, for publication on November 12 2019.

About SynAct Pharma

SynAct Pharma AB conducts research and development in inflammatory diseases. The company has a platform technology based on a new class of drug candidates aimed at acute deterioration in chronic inflammatory diseases with the primary purpose of stimulating natural healing mechanisms.