Pressmeddelande

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Approval for start of the clinical phase IIa study in patients with active arthritis

SynAct Pharma AB ("SynAct") today announces that both the Danish Medicines Agency and the Scientific Ethics Committee have authorized to conduct the planned clinical Phase IIa study with the drug candidate AP1189 in patients with active rheumatoid arthritis. The study is conducted as a randomized, placebo-controlled, double-blind study in which two doses of AP1189 are tested in addition to standard treatment in patients with newly developed active rheumatoid arthritis. The study is conducted in two parts. The first part focuses on safety and tolerability in patients to give an initial indication of effective dose range. The second part will focus on studying the effect of AP1189 on relevant disease parameters. The study will be initiated at clinics in Denmark during the summer of 2019 and the overall study will be reported at the end of 2020. Interim analysis at the end of the study's first part is planned to be reported end of the first quarter of 2020.

The planned clinical Phase II study of 90 patients entitled "A double-blind, multi-center, two-part, randomized, placebo-controlled study of safety, tolerability, and efficacy of 4 weeks of treatment with AP1189 in early rheumatoid arthritis (RA) patients with active joint disease", is approved by the Danish Medicines Agency and the Scientific Ethics Committee for implementation on rheumatological departments in Denmark. The study will be conducted with patients with active arthritis who are referred to the special department for treatment with antirheumatic drugs that treat diseases where first-line treatment is methotrexate. Methotrexate treatment is given in the study as an oral treatment in a standard dosing regimen, AP1189 or placebo therapy will be given as an adjunct to methotrexate treatment. The primary purpose of the study is to generate a safety profile for the drug in patients and the drug's ability to reduce disease intensity relative to placebo. The study is scheduled for four weeks of dosing and will be initiated at clinics in Denmark during the summer of 2019 with reporting of the overall study at the end of 2020. Interim analysis at the end of the study's first part is planned to be reported during the first quarter of 2020.

CEO Jeppe Øvlesen comments:
"We are very pleased that our application for the start of a clinical Phase IIa study with our First-in-Class candidate, AP1189, has been approved. The study will be carried out at rheumatologic departments in Denmark with planned first interim analysis results during the first quarter of 2020. With recently secured bridge loan financing, we maintain the company's momentum in an efficient manner in accordance with set goals - to achieve value-increasing activities. We are now looking forward to initiating the clinical Phase IIa study and increasing the commercial potential of AP1189 and demonstrate that our new and very interesting "inflammation resolution" approach may benefit patients not adequately served with the presently available "immunosuppressing" drugs."

For further information about SynAct Pharma AB, please contact:

Jeppe Øvlesen
CEO, SynAct Pharma AB
Phone: +45 28 44 75 67
Mail: joo@synactpharma.com

Thomas Jonassen
CSO, SynAct Pharma AB
Phone: +45 40 15 66 69
Mail: tj@synactpharma.com

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 June 10 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.