SynAct Pharma completes part 1 of clinical phase II study with AP1189 in Rheumatoid Arthritis

SynAct Pharma AB ("SynAct") today announced that dosing of the leading candidate drug AP1189 was successfully completed in the second cohort (100 mg dose level) in part 1 of the company's Phase IIa study in patients with Rheumatoid Arthritis (RA) with high disease activity.

A data review on blinded non-validated data from 15 patients in the cohort of 100 mg dosing suggests that the compound is safe and well tolerated and shows that two thirds of the patients (10/15 patients) had a reduction in disease activity from severe to moderate or low disease activity during the 4 weeks treatment period. The median CDAI for these patients was 14.5. The remaining third of the patients (5/15) had continued high disease activity with a median CDAI of 30.

The decision of which dose(s) to be tested in part two of the study, will be taken following recommendations from an independent data monitoring board who will get access to un-blinded and validated data from part one of the study. Key information from the recommendation for dose selection will be communicated to the public in November.

Following completion of a data review and decision on which dose(s) to be tested in second part of the study, the study will continue with recruitment at sites in Denmark, Norway and Sweden from November 2020. The aim is to complete the recruitment to the study in H1 2021. A total of up to 90 patients will be included in both parts of the study.

The study is designed as a placebo-controlled double-blind multicenter study with a 2:1 randomization ratio of once-daily dosing of AP1189 vs placebo in RA patients referred to rheumatological departments due to uncontrolled disease activity defined as clinical disease activity index (CDAI) higher than 22. AP1189 or placebo is given once daily for 4 weeks in parallel with the initiation of a treatment with the disease-modulating, anti-rheumatic drug methotrexate.

"These findings are very exciting and in line with what was reported from the first cohort dosed with 50 mg. We have to emphasize that we can neither exclude that there are placebo treated patients among those who show a reduction in disease activity, nor that there are patients treated with AP1189 among those who show continued high disease activity," said Thomas Jonassen, CSO at SynAct Pharma.

Following the successful exercise of the warrants of series TO 2 in July 2020, SynAct has funding for the continued clinical development of the AP1189 compound in Phase II in the ongoing studies in RA and Nephrotic Syndrome, as well as a study in Covid-19 patients to be conducted in the new RESOVIR collaboration setup together with key opinion leaders within resolution therapy.

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 below contact person, for publication on October 12, 2020.

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About SynAct Pharma AB

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. For more information, please visit https://synactpharma.com.

About AP1189

The mechanism of action of SynAct Pharma´s lead compound AP1189 is to promote resolution of inflammation through melanocortin receptor activation directly on macrophages, thereby reducing the pro-inflammatory activity of macrophages and by stimulating so-called macrophage efferocytosis, a specific ability to clear inflammatory cells (J Immun 2015, 194:3381-3388). This effect has shown to be effective in disease models of inflammatory and autoimmune diseases and the clinical potential of the approach is currently tested in a clinical phase 2 study in patient with active Rheumatoid Arthritis, in Nephrotic Syndrom and COVID-19 inflammation ARDS. https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1)

https://clinicaltrials.gov/ct2/show/NCT04456816?term=AP1189&draw=2&rank=2