SynAct Pharma completes patient recruitment to the Phase 2a BEGIN study of AP1189 in early severe Rheumatoid Arthritis

SynAct Pharma AB ("SynAct") today announced that patient recruitment to its Phase 2a clinical evaluation of the company's lead candidate compound, AP1189, in early Rheumatoid Arthritis (RA) patients with severe disease activity, the BEGIN study, has been completed.

With all patients included into the study, dosing will be concluded in October with the last patient's safety follow-up visit to be conducted in November. SynAct therefore anticipates releasing top-line study data by end of November 2021. SynAct wishes to thank our clinical sites, investigators, their staff, and most of all the patients for fully enrolling this trial despite challenges posed by the COVID-19 pandemic.

Key results with focus on the primary efficacy readout and safety, from the full data set, will be presented in a press release followed by an investor call when the data is available. The company will continue to update the market on the further progress and the process to finalize the BEGIN study.

"I am glad that we now can announce that the last patient has been enrolled. Recruitment during the pandemic was challenged by a lower rate of referrals to investigator clinics as well as local COVID-19 measures that put constraints on activities related to clinical trials. We kept recruitment open until the targeted number of patients were randomized to, hopefully, ensure statistical significance in the full data set. We are excited to see the full data and hope that it further establishes the potential of AP1189 in the treatment of RA," said Thomas Jonassen, CSO of SynAct Pharma. "Ongoing safety challenges with key classes of RA therapeutics underscore the need for new treatment modalities. We believe that AP1189 has the ability to resolve chronic or excessive inflammation like that seen in this trial and hopefully avoid the safety issues encountered with other therapies."

The company will present AP1189 as a potential emerging novel treatment option for Rheumatoid Arthritis at the American Conference or Rheumatology's ACR Convergence 2021 with a presentation scheduled for November 9. The abstract is focused on clinical pharmacology and on initial trial efficacy data based upon the BEGIN study interim analysis.

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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: www.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 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 two clinical Phase 2a studies in patients with either active rheumatoid arthritis or the nephrotic syndrome.

About BEGIN

The BEGIN study is a multi-center, two-part, randomized, double-blind, placebo-controlled study evaluating two doses of AP1189 (50 and 100 mg given orally once daily) for four weeks against placebo as add-on therapy to methotrexate in patients with severe active RA.

The primary efficacy endpoint in the study is reduction in disease activity from severe (defined as clinical disease activity >22) to moderate or low disease activity within the four-week treatment period.

Interim data based on the evaluation of the first 26 patients demonstrate that 75% of patients treated with 100 mg and 67% of patients treated with 50 mg AP1189 reached the primary readout compared to 44% of the placebo treated patients within 4 weeks of treatment.

https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1)
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