SynAct Pharma expands AP1189 BEGIN study in Rheumatoid Arthritis

Lund, Sweden, May 4, 2021. SynAct Pharma AB ("SynAct") today announced that based upon the encouraging results seen in part 1 of the phase 2 clinical study BEGIN of AP1189, the company has decided to increase the study size in an effort to demonstrate statistical significance in the trial.

Topline data from part 1 of the BEGIN study with AP1189 in early rheumatoid arthristis (RA) demonstrated a 66-74% treatment effect for the 50mg and 100mg dose groups respectively (Part 1 primary endpoint attainment of: placebo - 44%, 50mg - 67% and 100mg – 75%, previously reported in November 2020).

Statistical power calculations based upon this data indicate that an additional 15-20 patients would provide approximately 90% power to reach statistical significance in the trial. SynAct anticipates that that these additional patients will be recruited, and topline data will be available by end of Q3 2021.

“We designed the BEGIN study as a proof of concept study to look for activity of AP1189 in early RA patients with severe disease activity. Based upon the data from the Data Safety Monitoring Board (DSMB) assessment of Part 1 of the study we anticipate that a relatively small increase in the number of patients in the study would give us the ability to demonstrate statistical significance in the trial” said Dr. Thomas Jonassen, CSO of SynAct Pharma.

“While increasing the study size will delay the topline readout, we believe that the ability to demonstrate significance in this trial is well worth the extra time. Despite the ongoing pandemic recruitment is going well and we are excited about making this change.”

Reporting of the key data is planned to take place in Q3 of this year and the company also plans to submit the study results for presentation at the American College of Rheumatology´s annual meeting in San Francisco in November 2021. This timing is of course dependent upon external conditions such as the ongoing COVID-19 pandemic but is based upon current recruitment rates and the anticipated performance of additional study sites as well as the reopening of study sites closed due to the pandemic.

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 contact person below, for publication on May 4, 2021.

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

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 targeting chronic inflammatory diseases characterized by dysregulated immune responses. SynAct Pharma is listed on the Spotlight Stock Market (ticker: SYNACT). 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 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 three clinical phase 2a studies in patients with active rheumatoid Arthritis, nephrotic syndrome and COVID-19 associated respiratory distress.

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

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

About BEGIN Phase 2 Study

The BEGIN study is a multicenter, two-part, randomized, double-blind, placebo-controlled, 4-week study with repeated doses of AP1189. The study population consist of newly diagnosed subjects with severly active RA (Clinical disease activity score, CDAI >22) who are candidates for methotrexate (MTX) treatment.

The first part of the study that now has been completed consisted of two cohorts. In the first cohort a total of 14 patients were treated with 50 mg AP1189 or placebo oral dosing once daily for 4 weeks as add on treatment to MTX naïve patients. The dosing of MTX given were in the range of 10-25 mg given orally once weekly.

In the second part of the study that was initiated in the week of November 9, 2020, 50 mg AP1189, 100 mg AP1189 or placebo given orally in a 1:1:1 randomization will be dosed once daily for 4 weeks as add on to MTX as in part 1 of the study. The study is being conducted at sites in Denmark, Sweden, Norway, Bulgaria and Moldova.