SynAct Pharma reports positive PK data on AP1189 tablets

SynAct Pharma AB ("SynAct") today announced that it has received positive data from the first part of the ongoing pharmacokinetic (PK) study of AP1189 following oral administration of AP1189 tablets to healthy volunteers.

Data from a single dose cross-over study in 12 healthy volunteers of dosing of 2 x 50 mg AP1189 Tablets vs 100 mg AP1189 Powder for Suspension (the formulation used in the current clinical phase 2 development program), demonstrates that relevant PK parameters are comparable following dosing tablets and oral suspension. The data supports use of tablets in upcoming clinical studies with AP1189. The data stems from Part 1 of the ongoing PK study SynActCS004, that will be concluded in H1 2022.

Dose-normalized exposure was similar between the tablets and the oral suspension as shown by a relative bioavailability geometric mean of 1. Variability between the subjects was low, including variation in data for maximum observed concentration (C_{max}), time to maximum concentration (T_{max}), area under the concentration-time curve (AUC), and terminal elimination half-life ($t_{½}$). PK parameters observed after administration of 100 mg AP1189 powder for suspension were consistent with those observed in the previous pharmacokinetic studies in healthy volunteers (Phase 1).

Further to the pre-clinical data including repeat dose data in non-rodents filed in the recent priority generating patent application (June 2021), these new human data supports that AP1189 can be administered as an oral tablet inducing fast release and absorption and thereby giving a favorable pharmacokinetic profile supporting once daily dosing.

“We are very pleased that these data from the human trial now confirm our expectations for the tablet and that we can directly correlate to and replace the oral suspension. We are convinced that this development will add tremendous value to the further development of AP1189 in various medical indications with high unmet medical need”, said Thomas Boesen, COO of SynAct Pharma.

SynAct intends to use the novel AP1189 tablet in the upcoming clinical trials, and thus tablets containing AP1189, and corresponding placebo have already been manufactured and released, and are undergoing regulatory studies to support the extended use of these.

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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 selective activation of melanocortin receptors 1 and 3. These receptors are located on all immune cell types including macrophages and neutrophils. Activation of these receptors results in two direct anti-inflammatory effects: it turns these cells to produce less pro-inflammatory molecules and also to switching them to perform inflammation “cleanup”, known as efferocytosis (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 clinical phase 2a studies in patients with active rheumatoid arthritis (RA), nephrotic syndrome (NS) and COVID-19. The safety and efficacy of AP1189 is being tested and has not been reviewed by any regulatory authority worldwide.

https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1
https://clinicaltrials.gov/ct2/show/NCT04456816?term=AP1189&draw=2&rank=2