SynAct Pharma completes clinical pharmacokinetic test of AP1189 tablet

SynAct Pharma AB ("SynAct") today announce that the company´s pharmacokinetic study on new tablet formulations of AP1189 has been successfully completed. The data confirms the tablet formulation as superior to, the until now used, AP1189 suspension. Further clinical development of AP1189 will be conducted using the new tablet.

The study was setup with three parts. In part 1 of the study, AP1189 formulated as fast release tablets, was tested in 12 healthy volunteers in cross over design with the previously used AP1189 suspension as control. The pharmacokinetic profile of the tablets was similar to that of the suspension with fast absorption and maximal plasma concentration reached within 2 to 3 hours following dosing. The exposure evaluated through area under the curve (AUC) was numerically higher on the tablet whereas the maximum exposure was almost identical between the two formulations. Three out of 12 subjects developed nauseas following dosing with the suspension, whereas no incidents of nausea following dosing with the tablets were reported.

In the second part of the study, the tablets were tested in a cross over design in 12 volunteers. On one occasion the tablet was dosed in the fasted state, at the other occasion the tablet was dosed following intake of a high fat diet. Dosing following intake of a high fat diet meal delayed the absorption of the compound meaning that time to maximal exposure was delayed by approximately 2 hours and the maximum concentration in plasma was lower (mean reduction by 33% compared to fasting state), whereas the overall exposure evaluated by AUC was only affected to minor degrees. These results are in line with what would be expected from the compound's physical and chemical characteristics and will not change the current dosing regimen.

In the third part of the study, dose linearity in the range of 50 to 300 mg was tested in 12 healthy volunteers. The data showed an almost ideal dose linearity with r^2 =0.99.

"The data generated on our new tablet formulation is very encouraging. The major purpose of developing the fast release tablet was to increase patient convenience with the hope that the exposure profile could be comparable to the profile after dosing with the suspension. The tablet exposure profile seems to be as attractive, if not better, than the suspension's profile. That the nausea present in a subset of subjects treated with the suspension seems to be absent following dosing with the tablet is a major achievement. We look very much forward to continue the development of our AP1189 compound using the new tablet", says Thomas Jonassen, CSO.

The information was submitted, through the agency of the contact person below, for publication at 08:00 CEST on May 4, 2022.

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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 “clean-up”, 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 programs in patients with 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.