SynAct Pharma doses first subject in study with new AP1189 tablets

SynAct Pharma AB ("SynAct") today announced that the first subject has been dosed in a clinical study in healthy volunteers to describe the pharmacokinetics of AP1189 following administration of a new tablet formulation aimed for once daily dosing in further clinical development of the compound.

The study is a single center, open label, 3-part pharmacokinetic study, with 12 healthy subjects in each part. The primary objective of the first part is to determine the relative bioavailability of AP1189 after dosing with the newly developed tablets versus the oral suspension used so far in clinical trials.

In the second and third part of the study, the food effect on the pharmacokinetics, which is a regulatory requirement, and proportionality following dosing at different dose levels will be evaluated.

"This is a crucial step in the development of AP1189. We are eager to see the results of dosing AP1189 as tablets to humans. We have succeeded in making AP1189 tablets that meet our expectations. Importantly, the manufacturing process allow for further development, including scaling as will be required for clinical development in later phases.", said Thomas Boesen, COO, SynAct Pharma.

Preclinical testing of the tablets supports that the pharmacokinetic profile of AP1189 in plasma is comparable or better after dosing of tablets than after dosing of the suspension currently used in the phase 2a clinical development, and when confirmed in humans, the tablets will be used instead of the suspension in future clinical trials.

"The new tablets will enable supply of AP1189 to a wider population of patients, with the aim to enhance safety and compliance. The new formulation shows unique characteristics with regard to compound release that has been covered in the IP application we filed in June and will give an additional level of protection on the AP1189 product once granted.", said Thomas Jonassen, CSO.

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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 active rheumatoid arthritis and in nephrotic syndrome.

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