APURANO Pharmaceuticals publishes results of its Phase-I trial SELECT I with the API ADEZUNAP

APURANO Pharmaceuticals – a technology leader in developing smart bio-nanotechnology drugs against chronic pain – today published its clinical phase I results SELECT I with ADEZUNAP, a smart bio-nanotechnology cannabinoid receptor agonist for the treatment of chronic pain.

The phase I, open-label clinical trial SELECT I in healthy male subjects was conducted to assess the pharmacokinetic and safety profile of the oromucosal cannabinoid agonist ADEZUNAP containing a lipid-based nanoparticle drug formulation standardized to Δ-9-tetrahydrocannabinol (THC). 12 healthy male subjects received a single dose of ADEZUNAP containing a total of 3.96 mg THC. Plasma samples were taken 10 min to 30 h post-dose for analysis of THC, as well as the active THC-metabolite 11-hydroxy-Δ-9-tetrahydrocannabinol (11-OH-THC).

A single dose of ADEZUNAP (12 sprays, 3.96 mg THC) resulted in a mean maximum plasma concentration (C_{max}) of 2.23 ng/mL and a mean overall exposure (AUC_{0-t}) of 7.74 h*ng/mL for THC. For the active metabolite 11-OH-THC a C_{max} of 2.09 mg/mL and AUC_{0-t} of 10.4 h*ng/mL was measured. The oromucosal cannabinoid receptor agonist ADEZUNAP did not cause psychotropic effects despite the relatively high dosage applied by healthy subjects. No serious adverse effects occurred. Overall, ADEZUNAP was well-tolerated.

Despite administration of a lower dose, higher AUC values were detected for the oromucosal cannabinoid receptor agonist ADEZUNAP compared to currently available drugs on the market. These comparatively higher blood levels did not cause psychotropic adverse effects. The oromucosal cannabinoid receptor agonist ADEZUNAP was well tolerated at a single dose of 3.96 mg THC. The oromucosal route of administration may provide an easily applicable and titratable drug formulation with a high safety and tolerability profile