Approval to conduct the 4 registration studies DISCOVER with ADEZUNAP

The European Medicines Agency (EMA) and all ethics committees involved have given us approval to conduct our 4 phase 3 registration studies DISCOVER with our nano cannabinoid 1 (CB1) receptor agonist ADEZUNAP. In previous clinical studies, ADEZUNAP has proven its superiority in absorption and safety compared to other cannabis medicinal products on the market. Real-world data show that ADEZUNAP is very well tolerated and effective.

From the end of June 2023, Apurano Pharmaceuticals will thus be conducting the largest clinical studies ever conducted against chronic pain with 2,232 patients.

DISCOVER is divided into 4 individual studies against 4 chronic pain indications:

• Chronic back pain

• Chronic post-surgical or post-traumatic neuropathic pain

• Chronic painful diabetic polyneuropathy

• Chronic central pain such as after a spinal cord injury, stroke or multiple sclerosis

In accordance with EMA and FDA guidelines, if DISCOVER is successfully implemented, we will receive market approval for all chronic pain indications and thus market access to more than 60 million patients in the EU and 40 million patients in the USA.

Prof. Dr. dr medical Tölle from the Klinikum Rechts der Isar at the Technical University of Munich is in charge of the DISCOVER studies. More than 50% of all university clinics in Germany and Austria and many other pain centers take part in the DISCOVER studies.

DISCOVER is divided into an approval part of 4 months and a seamless benefit assessment part. The study lasts a total of 1 year. The study design was created in various consultations with the BfArM, the EMA and the G-BA and is therefore being carried out for the first time according to the latest requirements as a so-called add-on study. This means that ADEZUNAP must prove the additional benefit compared to the appropriate comparator therapy (standard pain medication). The current standard pain medication did not have to face this challenge. The DISCOVER study design thus meets the requirements of the benefit assessment regulation.

Here is a current newspaper article on the DISCOVER registration studies:
https://www.merkur.de/lokales/muenchen/cannabis-gegen-schmerzen-neuer-ansatz-fuer-weltweite-grossstudie-zr-92197383.html