BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

APRINOIA announces NMPA approval to initiate Ph 3 clinical trial

October 28, 2020 | News

The objective of Phase 3 clinical trial is to evaluate the safety and effectiveness of [18F]-APN-1607



APRINOIA Therapeutics advancing a pipeline featuring diagnostic and therapeutic programs, collectively targeting brain disorders has recently announced that China National Medical Products Administration (NMPA) had approved to initiate Phase 3 clinical trial to evaluate APRINOIA's positron emission tomography (PET) imaging tracer, [18F]-APN-1607, targeting abnormal tau protein aggregates in brains of patients of cognitive impairment.

[18F]-APN-1607 is a new generation tau PET imaging tracer with improved selectivity and off-target binding profiles. It is designed to specifically recognize tau proteins in their pathological aggregated states, but not normal physiological ones.

The objective of Phase 3 clinical trial is to evaluate the safety and effectiveness of [18F]-APN-1607 to differentiate patients with Mild Cognitive Impairment (MCI) and different stages of Alzheimer's disease (AD) from healthy subjects. The proposed trial will enroll approximately 230 subjects with all receiving [18F]-APN-1607.

Pathological tau proteins are associated with neurodegeneration in AD, as well as in other tau-related brain disorders, a.k.a. tauopathies, including progressive supranuclear palsy (PSP) and corticobasal degeneration (CBD). Tau abnormality has been recognized as a key biomarker to characterize those tauopathies. [18F]-APN-1607 could quantify and visualize tau burden and distribution in all those tauopathies, offering broader clinical utilities.