

NEUREVO completes successful scientific advice meeting with the German Medicines Agency for NEUREVO's product in acute stroke

Scientific Advice Meeting with the German Medicines Agency (BfArM), resulted in a positive assessment and a confirmation of NEUREVO's strategy to advance NEUREVO's stroke program to FiH clinical trials

Today, NEUREVO announces that the company has successfully completed a scientific advice meeting with assessors of the German Medicines Agency (BfArM), in which the non-clinical data package and NEUREVO's plans for First-in-Human clinical trials of NEUREVO's pipeline program for patients with acute stroke has been presented.

The assessors from BfArM including experts for non-clinical development, safety, clinical and manufacturing (chemistry, manufacturing and controls, CMC) have essentially agreed with the quality of the already performed preclinical program (including data on efficacy, safety and CMC) and the presented clinical-trial-enabling development strategy of NEUREVO to advance its product candidate to First-in-Human clinical trials in acute stroke patients. Only a final GLP-toxicity study in rats is pending as part of the necessary non-clinical evaluations to start the FiH clinical trials.

The scientific advice meeting at the BfArM has therefore cleared NEUREVO's strategy for the initiation of FiH clincial trials for NEUREVO Stroke therapy pipeline program in acute stroke.