



Mallinckrodt Halts Phase 2b Acthar Gel Trial

Mallinckrodt is permanently halting its Phase 2b PENNANT Study (MNK14042068) investigating the safety and efficacy of a hormone injection for the treatment of ALS.

Acthar Gel is a highly purified preparation of Adrenocorticotrophic hormone (ACTH) injected either beneath the skin or into the muscle. It is approved by the FDA for the treatment of 19 indications including acute exacerbations of multiple sclerosis in adults.

The PENNANT Study MNK14042068 was a double-blind, placebo-controlled Phase 2b study evaluating the efficacy and safety of Acthar Gel in the treatment of ALS. Participants were randomly assigned to either Acthar Gel or a placebo in a 2:1 ratio. The study was designed with a double-blind treatment period of 36 weeks with the primary efficacy endpoint at week 36, after which, participants could continue in a 48-week, open-label extension in which all participants receive Acthar Gel.

The independent Data and Safety Monitoring Board made the decision to end the trial after careful analyses indicated a specific concern for pneumonia, a serious condition in people with ALS. The board concluded that taking Acthar Gel was too high a risk for people with ALS due to an increased risk for pneumonia as the disease progresses.

Read Mallinckrodt's press release [here](#).

The board also took into consideration that the participants who completed week 36 of treatments were not provided a definitive determination of treatment effect. This added to the recommendation for study termination.

Study sites are currently being directed to end the study and follow specific instructions on how to safely discontinue treatment in participants currently in the study. This includes information on the risks of abruptly halting medication.

While it is not unusual for trials to be halted, The ALS Association is disappointed to hear this news. We remain hopeful that the active research pipeline will yield effective treatments as soon as possible. There are currently at least 35 interventional trials for ALS underway.

For more information about the trial and trial sites, click [here](#).