CASE STUDY

ACM GLOBAL LABORATORIES

Supporting Successful Phase 3 Clinical Trial for PGTCS Seizure Disorder Treatment through Custom Programming and Safety Protocol Management

BACKGROUND

ACM Global Laboratories was approached to be a central lab for a Phase 3 clinical trial of a new therapy for primary generalized tonic-clonic seizures (PGTCS). The primary study objective was to demonstrate the efficacy of the new treatment vs. a placebo as adjunctive therapy for uncontrolled PGTCS, with the secondary objective being the assessment of the safety and tolerability of the treatment in subjects with idiopathic generalized epilepsy (IGE) with uncontrolled PGTCS.

Epilepsy & Tonic-Clonic Seizures (PGTCS)

Epilepsy is the second most prevalent neurological disorder in the world, and it is estimated to affect almost 70 million people worldwide.[1] Epileptic seizures occur in the context of a wide range of epilepsy syndromes that may be of genetic, structural/metabolic, or of unknown origin. The most common seizure type in patients with epilepsy is partial seizures (57%), followed by tonic-clonic (23%), absence (6%), and myoclonic (3%); the latter 3 seizure types comprise the majority of generalized seizures (convulsive and nonconvulsive).[2]

PGTCS is a type of seizure that occurs all over the brain, affecting both sides of the brain from the start, causing muscles to stiffen and convulsions to occur for up to a few minutes. People living with generalized tonic-clonic seizures have an increased risk of injury and those who experienced three or more in one year had a fifteen-fold increased risk of sudden unexpected death in epilepsy. Treatment of PGTCS is complex because the patient population with PGTCS is heterogeneous, as PGTCS can occur as an isolated seizure type or in association with other generalized seizure types.

PROCESS

This was a globally conducted double-blind study to evaluate the efficacy and safety of the treatment as adjunctive therapy for uncontrolled PGTCS in subjects with IGE. ACM facilitated the investigators' ability to monitor patient safety through custom programming. Test methods included standard safety panels, HIV, Thyroid panel, and PDILI (Potential Drug-Induced Liver Injury) testing kits.

FACTORS OF SUCCESS

Seamless Clinical Integration & Customized Solutions are Critical for Success

At ACM we know that every trial begins well before they reach our lab—we also know that transitioning assays and testing methods used in the nonclinical lab into the clinical phase is key to the success of the trial. That's why with every study we develop customized testing solutions drawn from our portfolio of laboratory support services that allow our scientists to develop and transfer methods accurately and efficiently to meet the needs of our clients.

Partnering With ACM

As the clinical trial landscape evolves, we pride ourselves on being able to manage trials with increasing complexity, including studies with new and unique biomarkers, companion diagnostics, and adaptive designs. We provide both the scientific expertise and the process management across the breadth of development including end-to-end lab service solutions, kit creation and delivery, sample tracking, chain of custody, logistics, and commitment to quality.

RESULTS

Overall the results of this trial were encouraging and successful, and the treatment was proven to be generally tolerated in patients with both IGE and PGTCS. This has led the U.S. Food and Drug Administration to approve it for use in the United States - an exciting development for those whom the treatment will ultimately be administered to, and an accomplishment for ACM Global Laboratories, our clients and extended team members.

1. *Ngugi et al, 2011*
2. *Hauser et al, 1993*