Synteract Exceeds
NeurAxon Expectations in Migraine Clinical Trials

Highlights

- Synteract partnered with NeurAxon on two Phase II studies of its lead compound.
- Both Phase II migraine studies completed enrollment earlier than scheduled.
- Synteract named NeurAxon's primary CRO provider, working on 10+ studies in multiple pain indications.

Introduction

NeurAxon is a pharmaceutical company headquartered in North America, focused on developing novel pain management solutions. Synteract partnered with it for the development of its first compound in 2007, and has since been named its primary provider of CRO services, working on over 10 studies with two different compounds in multiple pain indications. In 2009, Synteract partnered with NeurAxon to

execute two Phase II studies to evaluate safety and efficacy of its lead compound in migraines with and without aura. Trials were conducted in the U.S. and Canada.

Challenges

- Enrollment timelines were critical to the company and investors.
- Synteract was handling two similar studies for NeurAxon simultaneously. Patient enrollment occurred quickly so resources needed to be carefully managed to maintain study progress and ensure data collected was of the highest quality.
- The study drug itself was being provided to the subjects to self-administer at home. Sites needed to oversee compliance.

Our Solutions

- To capture efficiencies across the similarly designed studies, a comparable project team structure was adopted to share best practices yet function independently.
- To manage monitoring at the pace needed to achieve study objectives, regional monitoring teams were arranged to reduce travel and allow for flexible visits. "Floating" monitors could also supplement efforts at sites with heavy workloads or competing demands.

- With enrollment timing the most critical factor impacting success, Synteract identified primary site lists with a 30% overage to proactively replace underperforming sites as needed while maintaining study momentum.
- To manage patients administering medications from home, Synteract deployed an IVRS solution that tracked randomization and dosing of subjects. The system alerted sites after a patient had dosed and needed follow-up.

Program Success

- Both Phase II migraine studies completed enrollment earlier than scheduled.
- The IVRS solution allowed Synteract to carefully track the exact number of doses in real time and manage the expected workload at sites.
- With the Phase II studies completed, Synteract and NeurAxon continued their partnership with the development of NeurAxon's second drug candidate.

About Synteract

Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of expertise in oncology, general medicine, dermatology, and neuroscience indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Therapeutic-Expertise/Neuroscience or ContactUs@synteract.com.

Synteract.com

BRINGING CLINICAL TRIALS TO LIFE™