GW Pharmaceuticals (GWPH) Spasticity Trial: Phase III (RESERVE Trial)

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GW Pharmaceuticals (GWPH) has recently began a phase III trial of their drug, Sativex, or Sativex-C5 (APE5-C5), for the treatment of spasticity (spasticity has a relative meaning of muscle cramping and involuntary muscle contractions). In Sativex, GW is attempting to use traditional Chinese medicine to reach millions of people living with neuropathic pain and has stated that Sativex could help an estimated 10 to 15 million patients suffering from neuropathic pain worldwide.

GW Pharmaceuticals is a rare disease drug company founded in 1998 to develop drugs that modify RNA and enhance the bodyâ€™s own ability to eliminate disease-causing proteins. The currently approved drug on the market from this company (Cannabinoid receptor system agonist GW135/Selazine) is used to treat multiple sclerosis (MS). This drug would have seemingly entered the cancer drug market by combining Sativex with chemotherapy drugs.

The results of this drug trial is that 40 people, ages 20 to 70 years old who suffered from MS, have completed one to three years of treatment. The trial, known as the Blindfolded Shoot For the Cure Trial, evaluated the safety and efficacy of Sativex in the treatment of SMA patients. SMA is a disease affecting one in every 3,000 to 4,000 children. SMA is an inherited neuromuscular disorder that is a progressive, chronic, and life-long disease. SMA is caused by a deficiency in either AOD (Alkaloids adenine dinucleotide) or IOD (amino acid residues) and a loss of the genetic protein that normally controls protein folding in the body.

The trial consisted of two groups of 30 patients each. One group was treated with 30mg of Sativex every two hours as well as 20 mg of the drug for five days in the middle of the day. This group reported on AOD levels and report of muscle cramps, as well as no reports of food side effects. Their symptoms improved a great deal and began to decrease from week 1 to week 30. In addition, reports from those involved in the study told of some cases of remarkable pain relief. After one year the Sativex treatment improved the symptoms of the children in the study greatly.

However, the results of this trial are still not statistically significant. Only one of nine subjects (5%) achieved statistical significance on the primary outcome measure (the mean of their movements during their testing, compared to baseline) for both AOD and IOD levels. In terms of protein folding, they were much worse than baseline. All subjects who had received a majority of Sativex in addition to injections of glucocorticoids reported significant reduction in their muscle cramps. AOD levels did not show any clear improvement, and the IOD levels were much worse compared to baseline and the previous study. Therefore, a 50 to 60% reduction in muscle cramps cannot be made to prove that Sativex is more effective than other treatments and cannot be considered an independent outcome. In addition, the 5 milligram, 2.5 mg and 20 mg dose groups experienced similar treatment effects at 60 weeks.

The Phase III trial for the management of SMA is due to be completed by August 2012. Results of this study will be required to be validated by the National Institute of Neurological Disorders and Stroke (NINDS). If the trial is not completed in a statistically significant manner, the FDA may refuse to grant Sativex a license. If the trial is successful, GW Pharmaceuticals plans to file an Investigational New Drug (IND) application and seek a license to manufacture the drug in the United States.

Abstract #77: Sativex-C5 for Allergic Rhinosinusitis â€“ Effects of Sativex on Patient Behaviors in Epilepsy and Neurological Disorders

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A Fire Hydrant In The Middle Of A Forest