Medivation to Begin a Phase III Trial of Dimebon

Medivation, in collaboration with Pfizer, is sponsoring a randomized, double-Blind, placebo-controlled, phase III trial of Dimebon in HD patients with mild to moderate Huntington's Disease. Recruitment will begin this year.

Dimebon was developed and sold as an antihistamine in Russia two decades ago. Newer antihistamines have replaced it but Russian scientists discovered that the drug has neurologic properties and identified it as a potential treatment for Alzheimer's Disease (AD). Medivation licensed the drug and also began researching its potential for Alzheimer's disease; a Phase III trial for AD patients is ongoing.

Medivation also decided to look at its potential for Huntington's Disease since both diseases involve progressive neurodegeneration and have various pathologies in common such as abnormal protein accumulation and abnormal mitochondrial function. The results of a Phase II study in HD patients completed in 2008 encouraged Medivation to conduct the Phase III study. Dimebon was found to be safe and well-tolerated in Huntington's patients and cognition improved in the treatment group compared to the placebo group as measured by the Mini-Mental States Examination (MMSE).

The primary measure of effectiveness in the Phase III trial will be the results of the MMSE. The researchers will also look at the cognitive subscales of the United Huntington's Rating Scales although they may not change very much since the Scale is more sensitive to decline than improvement. A battery of cognitive tests will be administered at some of the sites to further explore what parts of cognition are improving. Researchers will look at overall functioning as well and of course safety will be monitored.

Approximately 50 research centers across North America, Europe, and Australia, will enroll approximately 350 individuals for a six month trial. The Huntington Study Group will be the respository for all the data and provide the sites in North America. EHDN is going to select the sites in Europe. Dr. Karl Kieburtz is the principal investigator (PI) and Dr. Bernhard Landwehrmeyer is the co-PI. There are also sites in Australia which will work directly with Medivation.

"This trial is exciting because it's an international effort," said Dr. Kieburtz. "This is the first time that we have had global collaboration on a clinical trial for Huntington's Disease."

Prospective participants should keep checking at the Huntington Study Group website where site locations and contact information will be posted as sites are ready for recruitment.

- *Marsha L. Miller, Ph.D., June 3, 2009*