

Tolperisone disappoints in phase IIb study in spasticity

Tolperisone has garnered disappointing results in top-line data from a phase IIb study aimed at assessing the drug's use in spasticity associated with multiple sclerosis (MS).

The trial was conducted in 27 MS centres in Germany and other European countries to evaluate the safety, tolerability, pharmacokinetics and efficacy of tolperisone in up to 150 MS patients with spasticity.

Results showed that the study did not achieve statistical significance on its primary endpoint of a reduction from baseline in patients' Ashworth scores* as compared with placebo. Moreover, the reduction of muscle spasm, a secondary endpoint, also failed to achieve statistical significance. There were no safety issues associated with tolperisone, the trial was adequately powered, and all statistical parameters were in line with expectations.

* a measure of increased resistance to passive limb movement

Avigen Inc. Avigen Announces AV650 Did Not Meet Efficacy Endpoints in Phase 2b Clinical Trial for Spasticity in Patients With Multiple Sclerosis. Media Release : 21 Oct 2008. Available from: URL: <http://www.avigen.com> 809094247