Allergan: new data suggest Botox treats chronic migraine

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Phase III Botox trials show positive results for the treatment of headache in chronic migraine.

Top-line Phase III clinical trial data of Botox for the prophylactic treatment of chronic migraine showed a statistically significant decrease in the number of headache days at 24 weeks. Depending on full data results expected in mid-2009, Botox could become the first approved treatment for this debilitating and largely underserved condition.

Recently revised in the second edition of the International Classification of Headache Disorders (ICHD-2), chronic migraine is defined as 15 or more headache days per month over the past three months, with at least eight headache days per month that meet the criteria for migraine without aura, or that respond to migraine-specific treatment. According to Allergan, chronic migraine affects an estimated 1.2 million to 3.6 million people in the US, and while Johnson & Johnson's Topamax (topiramate) has quickly become the first-line prophylactic migraine choice for many prescribers, Botox represents the first therapy to be investigated specifically for chronic migraine.

Top-line data were announced from two Phase III clinical trials in which patients were randomly assigned to treatment with Botox or placebo injections every 12 weeks. The primary analysis was performed at week 24, following two treatment cycles. Both studies showed a decrease in the number of headache days (the FDA's preferred efficacy measure) that was significantly greater in patients receiving Botox than in patients receiving placebo ($p=0.006$ and $p<0.001$).

Although no specific safety data were announced, Allergan said that Botox injections at fixed-sites in varying locations including the forehead and temples were well tolerated. With off-label use of Botox for headache already common, this top-line data announcement may stimulate physician curiosity and drive prescribing knowledge prior to the announcement of full data and the potential attainment of a specific indication approval.

After a supplemental biologics license application is filed with the FDA by mid-2009, Datamonitor predicts a potential US launch in 2010, with the company targeting the EU market shortly after. Although the small number of patients who experience at least 15 migraine headaches per month limits Botox's target population, a serious lack of effective and well tolerated prophylactic medications (particularly for chronic migraine), together with strong public brand awareness, will result in the product addressing an important unmet medical need.

Source: Datamonitor