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Will your abstract be featured in a press release prior to the 2010 Annual Meeting? No

Press Release Explanation:

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UUP Description: OnabotulinumtoxinA for the treatment of chronic migraine

Title: OnabotulinumtoxinA for Treatment of Chronic Migraine: Analysis of the 56-Week PREEMPT 1 Trial

OBJECTIVE: Evaluate efficacy and safety of onabotulinumtoxinA (BOTOX®) as headache prophylaxis for adults with chronic migraine (CM).

BACKGROUND: CM is a disabling, undertreated, complex neurologic headache disorder. Few preventive treatments have been investigated; none are indicated for CM.

DESIGN/METHODS: Phase 3, 24-week, double-blind, placebo-controlled study, followed by 32-week, open-label phase. Qualified subjects were randomized (1:1) to onabotulinumtoxinA (155 U-195 U; n = 341) or placebo (n = 338) injections every 12 weeks for 2 cycles, followed by onabotulinumtoxinA (3 cycles). Efficacy variables evaluated were mean change from baseline in

frequencies per 28 days of headache episodes (primary endpoint), headache days, migraine/probable migraine (M/PM) days, M/PM episodes, and acute headache medication intake.

RESULTS: There was a statistically significant between-group imbalance at baseline in mean frequency of headache episodes ($p=0.023$) and M/PM episodes ($p=0.006$). Despite large within-group decrease from baseline, no significant between-group difference was observed at Week 24 for headache episodes (-5.2 onabotulinumtoxinA/ -5.3 placebo; $p=0.344$), M/PM episodes ($p=0.206$) or acute headache medication intake ($p=0.795$). Significant improvements from baseline were observed for headache days ($p=0.006$) and M/PM days ($p=0.002$) favoring onabotulinumtoxinA. At Week 56, there were significant within-group improvements from baseline for all efficacy variables. Treatment-related adverse event (AE) rate for all patients over the entire 56-week study was 29.7%. Total incidence of AEs was 70.3%, with a low rate of serious AEs (7.3%). Few discontinuations resulted from AEs (3.9%). Overall AE rate and incidence of treatment-related AEs decreased with subsequent onabotulinumtoxinA treatments.

CONCLUSIONS/RELEVANCE: Despite large within-group decrease in headache episodes (primary variable), no post-treatment between-group difference was seen through Week 24. OnabotulinumtoxinA (versus placebo) significantly reduced headache days and M/PM days through Week 24. At the end of the open-label phase there was a significant reduction from baseline across all efficacy variables. Repeat treatment with onabotulinumtoxinA was safe and well tolerated.

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