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Press Release Title: New Drugs Offer Hope for Migraine Prevention

Abstract Title: CGRP Monoclonal Antibody LY2951742 for the Prevention of Migraine: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study – Clinical Trials Plenary Session

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Objective: We evaluated the efficacy and safety of LY2951742, a fully humanized monoclonal antibody to calcitonin gene related peptide for migraine prevention.

Background: Migraine remains poorly treated with few effective preventive medications available.

Design/Methods: Subjects with 4-14 migraine headache days (MHD) per month were enrolled in a double-blind, randomized, 12-week placebo-controlled trial of biweekly subcutaneous injections of LY2951742 (150 mg) versus placebo. The primary endpoint was the change in number of MHD per 28 day period assessed at 12 weeks; secondary end points were the change in headache days, migraine attacks, and responder rate.

Results: A total of 217 subjects were randomized and received LY2951742 (107) or placebo (110). The mean change in MHD at 12 weeks when compared to baseline was -4.2 (62.5% decrease) vs. -3.0 (42.3% decrease) for LY2951742 and placebo respectively (p<0.003). LY2951742 was superior to placebo for all secondary endpoints including headache days -4.9 vs. -3.7 (p<0.0117), migraine attacks -3.1 vs. -2.3 (p<0.0051), and responder rate 70% vs. 45% (OR 2.88 [CI 1.78 to 4.69]). An exploratory endpoint of complete responders (100% reduction in MHD) was 33.3% vs. 17.3% for LY2951742 and placebo respectively. Adverse events seen more frequently with LY2951742 than placebo included injection site pain, upper respiratory tract infections, and abdominal pain.

Conclusion: In subjects with frequent migraine headache, treatment with LY2951742 resulted in a significant decrease in the number of migraine headache days, headache days, and migraine attacks when compared to placebo. LY2951742 was safe and well tolerated. The safety and robust efficacy results in this study are promising and justify the conduct of larger, randomized, placebo-controlled, phase 3 studies and the expression of cautious optimism that a new era of mechanism-based migraine prevention is beginning.

Study Supported By: Arteaus