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Press Release Title: New Drugs Offer Hope for Migraine Prevention

Abstract Title: Randomized, Double-blind, Placebo-controlled Trial of ALD403, an Anti-CGRP Peptide Antibody in the Prevention of Frequent Episodic Migraine

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Objective: To evaluate the efficacy and safety of ALD403, a genetically engineered humanized anti-CGRP antibody (IgG1), for migraine prevention.

Background: Calcitonin gene-related peptide (CGRP) is crucially involved in the pathophysiology of migraine.

Design/Methods: Patients with 5 to 14 migraine days per month were randomized to receive a single intravenous dose of ALD403 1000 mg or placebo in a double-blind fashion. The primary endpoint was the mean change in frequency of migraine days from baseline to migraine days during weeks 5-8. Patients were followed for 24 weeks for additional safety and efficacy analyses.

Results: Of 174 patients randomized, 163 patients received either ALD403 (81) or placebo (82). There were no significant differences in baseline demographics or characteristics between the two treatment groups. The mean change in migraine days between weeks 5-8 and baseline was -5.6 days (66% decrease) for ALD403 vs. -4.6 days (52% decrease) for placebo (one-sided p = 0.03). The proportion of patients with a 50%, 75%, and 100% reduction in migraine days at 12 weeks for ALD403 and placebo was 60% vs 33% (p < 0.001); 32% vs 9% (p < 0.001); and 16% vs 0% (p < 0.001), respectively. There were no differences in the type or frequency of adverse events, vital signs, or laboratory safety data between the two treatment groups.

Conclusions: A single intravenous dose of ALD403 1000 mg demonstrated efficacy for the preventive treatment of migraine in patients with a high monthly frequency of migraine days. ALD403 was generally safe and well tolerated. These results support the conduct of larger randomized, placebo-controlled studies and may potentially represent a new era in disease-specific and mechanism-based preventive therapy for migraine.

Study Supported By: Alder Biopharmaceuticals