ANNENBERG CENTER FOR HEALTH SCIENCES
AT EISENHOWER
Imparting knowledge. Improving patient care.

POSTER
perspectives

PS42: Efficacy and safety of LY2951742 in a randomized, double-blind, placebo-controlled, dose-ranging study in patients with migraine

Oakes, T.[1]; Zhang, Q.[1]; Ferguson, M.[1]; Skljarevski, V.[1]; Martinez, J.M.[1]; Johnson, K.W.[1]; Schacht, A.L.[2]; Due, M.R.[1]; Goadsby, P.[3]; Dodick, D.W.[4]

[1]Eli Lilly and Company, Indianapolis, IN, USA; [2]Eli Lilly and Company, Greenfield, IN, USA; [3]King's College London, London, England, CA, GBR; [4]Mayo Clinic, Phoenix, AZ, USA

Background: The aim of Study I5Q-MC-CGAB was to evaluate the efficacy and safety of LY2951742, a monoclonal antibody to calcitonin gene-related peptide, in the prevention of migraine headache.

Methods: We conducted a randomized, double-blind, placebo-controlled study at 40 centers in the USA. Patients 18_65 years of age with 4 to 14 migraine headache days (MHD) and at least 2 migraine attacks per month were randomized (2:1:1:1:1) to placebo or 1 of 4 LY2951742 dose groups (5, 50, 120, and 300 mg) given subcutaneously once monthly for 3 months. The primary objective was to assess whether at least one dose of LY2951742 was superior to placebo in the prevention of migraine headache. Superiority was defined as a _95% posterior probability of greater improvement for any LY2951742 dose compared with placebo, as measured by the mean change from baseline in the number of MHD in the last month of the treatment phase. Analyses were conducted on an intent-to-treat population (ClinicalTrials.- gov, NCT02163993).

Results: Between July 24, 2014 and February 23, 2015, 410 patients were randomized to LY2951742 (n5273) or placebo (n5137). Compared with placebo, LY2951742 groups showed greater mean reduction in the number of MHD from baseline in the last month of the treatment phase, where the 120 mg dose of LY2951742 met the primary objective (24.9 versus 23.6 days for the LY2951742 and the placebo groups, respectively, p50.004). Two other LY2951742 doses were associated with statistically significantly greater improvement than placebo in the number of migraine headache days at Month 1 (for the 50-mg and 300-mg doses) and Month 2 (for the 300-mg dose). The overall change from baseline over 3 months in number of MHD was significant for both the 120 mg and the 300 mg dose groups (p50.018 for both). Treatment- emergent adverse events (TEAE) that occurred more frequently with LY2951742 than with placebo during the 3 month treatment phase (those with an incidence of _5% of LY2951742 treated patients and greater than that for placebo) included injection site pain, upper respiratory tract infections, nasopharyngitis, dysmenorrhoea, and nausea. Additional TEAEs that occurred during the 3 month post-treatment phase (those with an incidence of _2% of LY2951742 treated patients and greater than that for placebo), were back pain, sinusitis, bronchitis, urinary tract infection, influenza, neck pain, and pain in extremity.

Reprinted from the 58th Annual Scientific Meeting of the American Headache Society, held June 9–12, 2016, in San Diego, California.

Conclusion: These results provide evidence that monthly subcutaneous injection of LY2951742 is safe, well tolerated and efficacious in the prevention of migraine.