EVALUATION OF CARDIOVASCULAR RISKS IN ADULT PATIENTS WITH EPISODIC OR CHRONIC MIGRAINE TREATED WITH GALCANEZUMAB: DATA FROM THREE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIES

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Introduction: The objective of the study was to evaluate data related to cardiovascular (CV) events in patients with episodic or chronic migraine from double-blind, placebo-controlled studies of galcanezumab, a monoclonal antibody that binds to calcitonin gene-related peptide (CGRP). CGRP is a potent microvascular vasodilator and has a hypothesized protective role in CV health. Increased CV risks have been reported in patients with migraine.

Materials and methods: In 2similarly designed episodic migraine 6-month studies and 1 chronic migraine 3-month study, data from patients randomized (1:1:2) to subcutaneous injection of galcanezumab 120 mg/month (following initial 240 mg loading dose) or 240 mg/month or placebo were pooled and grouped into CV disease risk "yes" or "no" subgroups based on reported medical history at baseline. Potential CV treatment-emergent adverse events (TEAE), identified using standard MedDRA queries and medical review, and categorical changes in blood pressure (BP), pulse, and electrocardiogram (ECG) were evaluated using the Cochran Mantel Haenszel test. Changes from baseline in BP, pulse, and ECG were evaluated using the analysis of covariance model.

Results: At baseline, across all treatment groups, between 17% and 19% of patients were in the "yes" CV disease risk subgroup. Among treatment arms, the percentage of patients reporting ≥1 CV TEAE were low (<4%) and treatment-by-CV disease risk subgroup interactions were not significant. The same number of patients had CV-related serious adverse events in the galcanezumab 240 mg (n=3; acute myocardial infarction [MI], pulmonary embolism, and transient ischemic attack) and placebo (n=3; pulmonary embolism, deep vein thrombosis, and MI) groups and the events were not considered treatment-related; none occurred in the galcanezumab 120 mg group. LS mean and categorical changes from baseline in BP, pulse, and QTcF were similar across treatment groups.

Discussion and conclusions: No clinically meaningful differences were observed for CV TEAEs, BP, pulse, or QTcF between patients treated with galcanezumab or placebo.

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