Risk of hypertension in erenumab-treated patients with migraine in clinical trials and in the post marketing setting

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OBJECTIVE: To assess the risk of hypertension among patients with migraine treated with erenumab in clinical trials and the postmarketing setting. Since calcitonin gene-related peptide (CGRP) can mediate vasodilation, pharmacological inhibition of CGRP signaling can theoretically result in hypertension. The US Prescribing Information for erenumab, a CGRP- receptor antagonist for migraine prevention, was updated in May 2020 to include the risk of hypertension based on experience in the postmarking setting.

METHODS: Hypertension adverse events (AEs) were identified from the Amgen Clinical Trial and Global Safety Databases using the standardized MedDRA query (SMQ) for hypertension.

RESULTS: During the 12-week, double-blind, placebo-controlled, treatment phase across pooled phase 2/3 clinical studies (placebo [n = 1043], erenumab 70 mg [n = 893], erenumab 140 mg [n = 507]), the incidence of hypertension AEs (0.9%, 0.8%, 0.2%) and proportion of patients starting a new antihypertensive medication not taken at baseline (1.2%, 0.8%, 0.2%) were similar across treatment groups. Exposure-adjusted patient incidence of hypertension did not increase over time during open-label erenumab treatment up to 5 years. In the postmarketing setting from May 17, 2018 to January 31, 2020 (245,682 person-years exposure), 362 hypertension AEs (355 cases; 0.144 per 100 person-years) were reported; 158 (43.6%) with a medical history of or risk factors for hypertension. Time to onset was available for 121 hypertension AEs (33.4%); 56 (46.2%) occurred within 1 week of erenumab initiation (43 [35.5%] within 1 day). Most AE reports described a single instance of blood pressure elevation (91.7%) and lacked details of antihypertensive treatment administered (88.6%).

CONCLUSIONS: While clinical trials did not show increased risk of hypertension in patients treated with erenumab, hypertension has been reported with erenumab in the postmarketing setting. Given limitations of postmarketing AE reports, additional data are needed to fully characterize the nature of and extent to which hypertension is a risk associated with erenumab and other CGRP-pathway antagonists.

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