Improving to 4 or Fewer Monthly Headache Days per Month Provides a Clinically Meaningful Treatment Goal for Patients With Chronic Migraine

Robert G. Kanishek, Deborah I. Friedman, Joe Himan, Roger Cady

1Department of Neurology, University of Pittsburgh School of Medicine, Pittsburgh, PA; 2Departments of Neurology and Neurotherapeutics and Ophthalmology, University of Texas Southwestern Medical Center, Dallas, TX; 3Pacific Northwest Statistical Consulting, Woodinville, WA; 4Lundbeck LLC, Deerfield, IL; 5TRK Consulting, Ozark, MO; 6Bossier State University, Springfield, MO

Introduction

Migraine is a common and incapacitating neurological disorder estimated to affect 18% of adults worldwide.1

Methods

Study Design and Treatment Interventions

This was a 24-week, double-blind, placebo-controlled, parallel-group, active-controlled, randomized, multicenter study to evaluate the efficacy and safety of eptinezumab (intravenous 100 mg, 300 mg, or placebo) for the prevention of monthly headache days (MHDs) in patients meeting International Classification of Headache Disorders-3 (ICHD-3) CM criteria.11

Objective

Patients

The study included patients aged 18 years or older who met the following criteria: experienced ≥12 CM monthly MHDs for ≥12 months (ICHD-3 CM criteria).11

Results

Figure 1A. Patient Global Impression of Change (PGIC) Response by MHD Subgroups

Table 1. Percent of Patient-Months with ≤4 MHDs Across MHD Subgroups

Table 2. Percent of Patient-Months with ≤10 MHDs Across MHD Subgroups

Table 3. Percent of Patient-Months with ≤15 MHDs Across MHD Subgroups

Table 4. Percent of Patient-Months with ≤20 MHDs Across MHD Subgroups

Table 5. Percent of Patient-Months with ≤25 MHDs Across MHD Subgroups

Figure 1B. PGIC Response Across 0–28 MHDs

Figure 2. Patient-Identified Most Bothersome Symptom (PI-MBS) by MHD Subgroups

Figure 3A. Days of Acute Medication Use by MHD Subgroups

Figure 3B. Days of Acute Medication Use Across 0–28 MHDs

Figure 4. Headache Impact Test (HIT-6) Life Impact by MHD Subgroups

Acknowledgments

The authors thank the patients, employees of Lundbeck and one of its subsidiary companies at the time of the study, and health care providers and clarify meaningful treatment outcomes.

References


KEY POINTS

1. Migraine is associated with a substantial burden of illness that affects people most during their prime earning and family-building years.1

2. Overall, data from this post hoc analysis of PROMISE-2 suggest the use of 4 or fewer MHDs as a targeted treatment goal for patients with CM. Specifically, patients in PROMISE-2 who had ≤4 MHDs in the prior 4 weeks had a higher percentage of patient-months reporting “very much improved” and “much improved” on the PGIC and PI-MBS, and “little to none” or “some” HIT-6 life impact.

3. In addition, virtually none of the patients in the ≤4 MHD subgroup reported acute migraine medication use on ≥10 days. Further, the use of acute medication paralleled headache frequency, suggesting additional benefits to helping patients reach ≤4 MHD.

4. Treatment goals should be to get the patient to ≤4 MHDs rather than just focusing on a 50% reduction in monthly migraine frequency, which for patients with high migraine frequency may still be substantial. In addition, having clearly articulated treatment goals will help improve communication between patients and health care providers and clarify meaningful treatment outcomes.

CONCLUSION

In this post hoc analysis of patients improving to ≤4 MHDs achieved improved patient-reported outcomes with substantially decreased acute medication use, suggesting that 4 MHDs may be a useful treatment goal to be used by health care providers for patients with CM.