**Study Design**

**Figure 1. Study design.**

- **Randomization:** Patients were initially randomized (1:1:1) to quarterly fremanezumab, placebo, or monthly fremanezumab.
- **Study Assessments:**
  - Results are summarized by double-blind randomization group.
  - Change from baseline in monthly average number of headache days of at least moderate severity (MMD) during the DBP and OLE.

**Methods**

- **Patients:**
  - The FOCUS study included adult patients with CM or EM who had documented inadequate response to at least 2 prior classes of migraine preventive medications.
  - Patients with significant psychiatric issues that, in the investigator’s opinion, would compromise the patient’s ability to participate were excluded.

**Objective**

- **To evaluate the efficacy and tolerability of fremanezumab in patients with moderate to severe depression.**

**Results**

- **Change from baseline in MMD during the DBP and OLE:**
  - Placebo:
    - Week 0: 10.1 (5.5)
    - Week 4: 10.1 (5.5)
    - Week 12: 10.1 (5.5)
    - Week 24: 10.1 (5.5)
  - Fremanezumab (all patients received monthly fremanezumab):
    - Week 0: 5.4 (5.4)
    - Week 4: 2.6 (5.3)
    - Week 12: 0.6 (4.9)
    - Week 24: 0.4 (3.9)

- **Change from baseline in MHD during the DBP and OLE:**
  - Placebo:
    - Week 0: 30 (42)
    - Week 4: 30 (42)
    - Week 12: 30 (42)
    - Week 24: 30 (42)
  - Fremanezumab (all patients received monthly fremanezumab):
    - Week 0: 15 (27)
    - Week 4: 13 (25)
    - Week 12: 14 (33)
    - Week 24: 14 (33)

**Conclusions**

- Fremanezumab demonstrated sustained effectiveness based on reductions in monthly migraine days and monthly headache days in patients with chronic migraine (CM) or episodic migraine (EM), moderate to severe depression, and inadequate response to 2 to 4 prior migraine preventive medication classes over a period of up to 6 months.

- Fremanezumab was also associated with sustained improvements in the severity of depressive symptoms in this population with moderate to severe depression.

**Acknowledgments**

- Presented at the American Psychiatric Association (APA) Annual Meeting Online; May 1-3, 2021.

**References**