**Objective**

To report cardiac safety data and 2-week patient-reported satisfaction among patients who have completed FDO as part of the Gilenya®@Home program.

**Methods**

**Gilenya®@Home program overview**

FDO (fingolimod oral administration) is the first Gilenya® FDO program. Patients were encouraged to report all symptoms during the FDO procedure and cardiovascular life support. Patients were transferred to the ER if a prolonged QTc interval was recorded, or there is new onset second-degree (or higher) AV block.

**Baseline assessment before treatment initiation**

- **Resting EKG** is recorded, and if required, reviewed immediately (electronically)
- Relevant cardiac history is confirmed
- Baseline assessment results are reviewed by a cardiologist
- Baseline sitting HR, mean (SD), bpm 73.7 (11.7) 73.0 (9.7)

**Assessment at home, treatment initiation and the FDO procedure**

- **HR** is recorded at baseline and hourly for 6 hours and is used to monitor any abnormalities.
- Patients complete a baseline survey and if any item on the survey is not met, the FDO procedure continues.

**Cardiac safety**

- **Safety data** were collected on 1450 patients from the pooled phase 3 trials (fingolimod 0.5 mg) and were reported to the FDA in 2016. Cardiac safety data were collected on 80% of patients who received fingolimod in any setting.
- **HR** or AV conduction abnormalities were observed in 204 (3.5%) patients, of whom 200 (3.4%) had a stable heart block.
- HR was ≥45 bpm in 180 (3.0%) patients.
- **HR** was corrected for the following reasons:
  - Severe untreated sleep apnea
  - History of symptomatic bradycardia
  - Cerebrovascular disease
  - Congestive heart failure
  - Transient ischemic attack
  - Other symptoms of bradycardia
  - Baseline QTc interval ≥500 ms

**Adverse events**

- **Means CK** et al. JAMA. 2010;303(2):164-172.

**References**


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**Disclosures**

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