Cardiac Effects of Fingolimod in Patients With Multiple Sclerosis

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CONCLUSIONS
Results of this interim analysis of first-dose observation data in the FCCO study are consistent with previous studies.1,5–7 In the majority of patients, HR effects were transient and began to resolve approximately 6 hours after first-dose administration. In patients with previous MS treatments, n (%)

INTRODUCTION AND BACKGROUND
Fingolimod, a first-in-class sphingosine 1-phosphate receptor modulator, was the first oral therapy approved in the United States and more than 40 other countries for treatment of relapsing multiple sclerosis (MS).1

METHODS
Study Design
At treatment initiation, fingolimod induces a transient and generally benign reduction in heart rate (HR) that is maximal by 4–6 hours after the first dose and resolves with continued dosing.5–7

Patients
Patients with previous MS treatments, n (%) were randomized 3:1 to once-daily fingolimod 0.5 mg or standard-of-care DMT for 6 months.

REsulTs
Clinical Status After First-Dose Administration
The majority of patients (98.6% [n=772/783]) were discharged at 6 hours postdose.

RESULTS
Fingolimod 0.5 mg

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Change in HR After First-Dose Fingolimod
For the 6-month study, 790 patients were randomized to fingolimod treatment, and 783 received at least 1 dose of fingolimod; patients were mainly women (75.9%) and had a mean age of 46.0 years

Figure: Change in mean sitting HR after fingolimod-first dose administration

Table 1. Patient demographic and clinical characteristics

Table 2. Symptoms of bradycardia occurring within 2 days after first-dose fingolimod administration (%)

Symptomatic Bradycardia
Incidence of first-dose symptoms of bradycardia was detected following first-dose administration and observation: all bradycardia symptoms were mild except for 1 report of dizziness of moderate severity (Table 2). A total of 125 (16%) patients had bradycardia symptoms of potential clinical concern, and 3 (0.4%) patients had symptoms exceeding 30 minutes.

Table 3. Mean ECG findings occurring after first-dose fingolimod administration (%)

Clinical Status After First-Dose Administration

Fingolimod 0.5 mg

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Figure: Change in mean standing HR after fingolimod-first dose administration

There were 28 new ECG findings that differed from baseline ECGs. The most common new ECG findings included first-degree AV block (n=11 [8.0%]) and sinus bradycardia (n=10 [7.3%]) (Table 3).

Table 3. New ECG changes occurring after 6 hours post-dose (%)

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Table 4. Heart rate (HR) changes after first-dose fingolimod administration (mean ± SD)

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