Direct Healthcare Professional Communication

6th November 2017

Fingolimod (Gilenya®) – contraindications in patients with cardiac conditions

Dear Healthcare Professional,

In agreement with European Medicines Agency (EMA) and the Health Product Regulatory Authority (HPRA), Novartis would like to inform you of the following:

Summary

Warnings against the use of fingolimod (Gilenya) in patients with underlying cardiac disorders have been strengthened; fingolimod is now contraindicated in:

• Patients with myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attacks, decompensated heart failure (requiring inpatient treatment), or New York Heart Association (NYHA) class III/IV heart failure in the previous 6 months.

• Patients with severe cardiac arrhythmias requiring treatment with class Ia (e.g. quinidine, procainamide, disopyramide) and class III (potassium-channel blockers, e.g. amiodarone, sotalol, ibutilide, dofetilide) anti arrhythmic drugs.

• Patients with second-degree Mobitz type II atrioventricular (AV) block or third-degree AV block, or sick sinus syndrome, if they do not wear a pacemaker.

• Patients with a baseline QTc interval ≥500 milliseconds.

Background

Fingolimod is a sphingosine 1-phosphate receptor modulator approved as a single disease-modifying therapy in highly active relapsing-remitting multiple sclerosis for adult patients with:

- highly active disease despite a full and adequate course of treatment with at least one disease-modifying therapy
- rapidly evolving severe relapsing-remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

The risk of serious cardiac rhythm disturbances with fingolimod, including polymorphic ventricular arrhythmia (PVA), is already described in the product information. However, cases of PVA, including fatalities have been reported. Therefore, to minimise the risk of severe adverse events in patients with cardiac conditions, contraindications are being introduced. The warnings and precautions on the immunosuppressive effect of fingolimod potentially leading to serious infections and cancer are also being updated.

October 2017 – IEO2/GIL17-CNF040
Continued overleaf
For complete information on the side effects and risks with fingolimod and the related recommendations for use, please consult the summary of product characteristics (SmPC) and package leaflet.

Please report any suspected adverse reactions associated with the use of fingolimod in accordance with the national requirements via the national spontaneous reporting system to HPRA Pharmacovigilance, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Tel: 01 676 4971. Fax 01 676 2517. Website www.hpra.ie. E-mail: medsafty@hpra.ie

Gilena is subject to additional monitoring to allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

If you have any further queries please contact me Niamh.murphy@novartis.com or at 01 260 1255.

Yours Sincerely,

Niamh Murphy

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Medical Advisory, Neuroscience