## Direct Healthcare Professional Communication

18.10.2017

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

Dear Healthcare professional,

In agreement with European Medicines Agency (EMA) and Malta Medicines Authority, 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

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For complete information on the side effects and risks with fingolimod and the related recommendations for use, please consult the product information (summary of product characteristics (SmPC) and package leaflet).

## *Call for reporting*

▼Gilenya is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions and medication errors via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from http://www.medicinesauthority.gov.mt/adrportal and posted to:

Medicines Authority Post-licensing Directorate,
Sir Temi Zammit Buildings,
Malta Life Sciences Park,
San Gwann. SGN 3000.
Or sent by e-mail to postlicensing.medicinesauthority@gov.mt

Healthcare Professionals may also report any adverse events suspected to be associated with the use of Gilenya to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, by fax on +356 22487219 or e-mail at drug_safety.malta@novartis.com

Marketing Authorisation Holder: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7S4, United Kingdom.

Local Representative: Novartis Pharma Services Inc., Representative Office Malta.
Tel No.: +356 21222872

## *Company contact point*

If you have any further questions or require additional information please contact *Novartis Pharma Services Inc., Representative Office Malta, by phone on +35621222872 or e-mail at novartis.malta@novartis.com*

*23.10.2017*
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