12th March 2018

Zinbryta▼ (daclizumab beta): Marketing authorisation suspended in the European Union

Dear Healthcare Professional,

Biogen in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- The marketing authorisation for Zinbryta is suspended in the European Union. Zinbryta is being recalled in the European Union with immediate effect.
- This suspension follows cases of immune-mediated encephalitis and meningoencephalitis which have been reported in patients treated with Zinbryta.
- No new patients should start treatment with Zinbryta.
- Physicians should immediately contact their patients who are being treated with Zinbryta to discuss alternative treatment options.
- All patients discontinuing Zinbryta should be informed that adverse reactions may also occur up to 6 months after discontinuation and be advised to contact their physician immediately if any new symptoms such as prolonged fever, serious headache, nausea or vomiting occur.
- Other immune-mediated disorders, such as blood dyscrasias, thyroiditis or glomerulonephritis can occur.
- Patients discontinuing the product should be monitored at least monthly and more frequently as clinically indicated for up to 6 months after the last dose of Zinbryta.

Background on the suspension of the Marketing Authorisation

Zinbryta is a humanised IgG1 monoclonal antibody indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) who have had an inadequate response to at least two disease modifying therapies (DMTs) and for whom treatment with any other DMT is contraindicated or otherwise unsuitable.

Following reports of cases of encephalitis and meningoencephalitis in patients treated with Zinbryta, the European Medicines Agency has initiated a safety review of Zinbryta. As a consequence, the marketing authorisation has been suspended and a recall of the product from the European market has been initiated.

In parallel, Biogen has taken the decision to voluntarily withdraw the marketing authorisation for Zinbryta (daclizumab beta) in the European Union. Withdrawal of the marketing authorisation will occur while the EMA's safety review is ongoing.

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Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line:

  0800-731-6789 or
- by downloading and printing a form from the yellow card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point

Further information can be requested from Biogen by telephone (0800 008 7401), fax [+44 (0) 1628 501 010] or email (MedInfoUKI@biogen.com).

Annexes

Contact point details for further information are given in the product information of the medicinal product (SmPC and PIL) at http://www.medicines.org.uk/emc.

Yours faithfully

Dr Simon Beck
Medical Director, UK and Ireland

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