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October 2016

Direct Healthcare Professional Communication

BLINCYTO® ▼ (blinatumomab) – Risk of Pancreatitis

Dear Health Care Professional,

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

Summary

- Cases of pancreatitis, some life-threatening or fatal, have occurred in patients treated with BLINCYTO®▼ in clinical trials and in the post-marketing setting. High-dose corticosteroid therapy may have contributed, in some cases, to the pancreatitis.
- Patients should be closely monitored for signs and symptoms of pancreatitis, including physical examination, laboratory evaluation for serum amylase and serum lipase and abdominal imaging.
- BLINCYTO®▼ should be withheld if pancreatitis grade 3 occurs, then restarted at 9 micrograms/day after improvement to grade 1 and escalated to 28 micrograms/day after 7 days if pancreatitis does not recur.
- In the event of pancreatitis grade 4, permanent discontinuation of BLINCYTO®▼ should be considered.
- Patients should be advised to recognize features of pancreatitis such as upper abdominal tenderness and pain (made worse by eating), nausea and vomiting. They should be instructed to get medical advice if symptoms occur.

Further Information

BLINCYTO®▼ is indicated for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL).

A cumulative safety review of pancreatitis from clinical trials and post-marketing experience has been performed, following a serious case of pancreatitis in which symptoms subsided

after temporary withdrawal of BLINCYTO®▼ and recurred after resuming treatment (positive dechallenge/ positive rechallenge).

Twelve cases worldwide with events suggestive of pancreatitis (including acute pancreatitis, necrotizing pancreatitis and increased pancreatic enzymes) were retrieved, including one case with a fatal outcome and another reporting a positive dechallenge and positive rechallenge with BLINCYTO®▼ .

In the majority of cases, pancreatitis occurred within 12 days after starting BLINCYTO®▼ (median time to onset of 7.5 days) and in patients concomitantly treated with high-dose of steroid, previously treated with agents known to induce pancreatitis or with a pre-existing pancreatic disease.

As recommended by the EMA and national competent authorities, the summary of products characteristics and the package leaflet of BLINCYTO®▼ will be updated to reflect this new safety information.

Call for reporting

Please continue to report suspected adverse reactions (ADRs) with any medicine or vaccine to the MHRA through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard. 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 ▼ (such as BLINCYTO®▼)

It is easiest and quickest to report ADRs online via the Yellow Cards website: www.mhra.gov.uk/yellowcard. 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 section of the MHRA website

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

Reports can also be made to Amgen Europe B.V. by contacting Amgen UK/Ireland Drug Safety Department directly on 01223 436441.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Contact details

For any queries or additional information regarding BLINCYTO®▼, please contact Amgen UK/Ireland Medical Information on 01223 436441 or by email to gbinfoline@amgen.com.

Yours sincerely

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