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Kyprolis ® (carfilzomib) DHCP Letter

12.Dec.2019

Dear Healthcare Provider,

Title: Kyprolis (carfilzomib) – New Safety Information: Risk of Progressive Multifocal Leukoencephalopathy (PML) and Hepatitis B Virus (HBV) Reactivation

Kyprolis May Increase the Risk of Progressive Multifocal Leukoencephalopathy (PML)

Summary of the Issue

- Progressive multifocal leukoencephalopathy (PML) is a rare, often rapidly progressive demyelinating disease of the central nervous system (CNS) that is caused by the reactivation of John Cunningham (JC virus), a human polyoma virus.
- As of 30 June 2019, carfilzomib has been administered to an estimated 4,156 subjects in the Amgen Sponsored Clinical Trial setting and an estimated 126,638 patients world-wide in the post-marketing setting.
- As of 17 July 2019, 4 cases of PML have been reported in clinical trials and post-marketing reports in patients receiving treatment with Kyprolis.
- These cases have occurred in patients with prior or concurrent immunosuppressive therapy.

Actions Being Taken by Amgen

Amgen will update the Warnings and Precautions section of Kyprolis ® product labeling to include information regarding the risk of PML. The patient information leaflet will also be updated with this information.

Summary of Recommendations for Healthcare Providers

Healthcare providers are advised to monitor patients for any new or worsening neurologic, cognitive or behavioral signs and symptoms that may be suggestive of PML as part of the differential diagnosis of CNS disorders. If PML is suspected, patients should be referred to a specialist and appropriate diagnostic testing should be initiated. Discontinue Kyprolis if PML diagnosis is confirmed.

Kyprolis May Increase the Risk of Hepatitis B Virus (HBV) Reactivation

Summary of the Issue

- Cases of Hepatitis B Virus (HBV) reactivation have been reported in clinical trials and postmarketing reports in patients receiving treatment with Kyprolis.
- The frequency of HBV reactivation is 0.1% based on clinical trial data.

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Actions Being Taken by Amgen

Amgen will update the Warnings and Precautions and Adverse Reactions sections of Kyprolis ® product labeling to include information regarding the risk of HBV reactivation. The patient information leaflet will also be updated with this information.

Summary of Recommendations for Healthcare Providers

Healthcare providers are advised to test patients for HBV infection before initiating treatment with Kyprolis. For patients who are carriers of HBV, prophylaxis with antivirals should be considered. Carriers of HBV who require treatment with Kyprolis should be closely monitored for signs and symptoms of active HBV infection throughout and following the end of treatment. Consider consulting a specialist for patients who test positive for HBV prior to or during treatment with Kyprolis.

The safety of resuming Kyprolis after HBV reactivation is adequately controlled is not known. Therefore, prescribers should weigh the risks and benefits when considering resumption of therapy in this situation.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Contact details for adverse event reporting or to request further information. Any suspected adverse reactions should be reported immediately to local Amgen QPPV or the National Pharmacovigilance and Drug Safety Center

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Should you have any questions or require additional information regarding the use of Kyprolis, please contact Medical Information on +966 11 2799394 or by e-mail at: meamedinfo@amgen.com

Sincerely,

Nasser Alrajhi	Yasser Al-Ahmary	Dr. Sameh Rakha
Regulatory Affairs Head	Senior Associate Global Safety	Medical Director
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