

Dear Research Participant (or name):

Thank you for participating in our trial called E1A11, a randomized phase III trial of bortezomib, lenalidomide and dexamethasone (VRd) versus carfilzomib, lenalidomide and dexamethasone (CRd) followed by limited or indefinite duration lenalidomide maintenance in patients with newly diagnosed symptomatic multiple myeloma.

We are writing to you today because new potential risks/ side effects have been identified for participants using the drug carfilzomib.

- Progressive multifocal leukoencephalopathy (PML), a rare neurological condition caused by a virus called JC virus has been reported in patients receiving carfilzomib. This condition can cause clumsiness, progressive weakness, and visual, speech, and sometimes personality changes. The relationship of this finding to carfilzomib is not clear, as the patients who had PML and had received the drug, carfilzomib, had received many drugs in addition to carfilzomib. Your doctor will watch you closely for any of these symptoms and perform tests to diagnose whether or not you have PML.
- Reactivation of a virus that causes liver infection (Hepatitis B) has been observed in patients receiving treatment with carfilzomib. The relationship of this finding to carfilzomib is not clear, as these patients have received many drugs in addition to carfilzomib. Your doctor will perform tests if you have any symptoms of this liver infection.

Please consider this information carefully and discuss it with your study doctor, as it might affect your decision to continue as a research participant in E1A11.

You will be asked if you wish to continue participating in this study. If you decide not to continue your participation in this research study, you will not be able to continue to take carfilzomib. We would, however, ask that you allow us to continue to follow your health status.

You have been a very important part of this research study. What we learn from this study may improve the lives of people living with multiple myeloma. We greatly appreciate your participation in E1A11.

Do you wish to continue to participate in E1A11?

If you have not yet completed your study treatment with carfilzomib, please let us know your choice by checking one of the two options below:

_____ I agree to continue to receive study treatment with carfilzomib on E1A11.

_____ I no longer wish to receive study treatment with carfilzomib on E1A11.

If you no longer wish to receive study treatment with carfilzomib on E1A11, can we continue to collect information on your health status?

_____ Yes

_____ No

Patient Signature:

Print Name:

Date: