May 24, 2021

Dear Research Participant (or name):

Thank you for participating in our trial called EA9161, a randomized phase III study of the addition of venetoclax to ibrutinib and obinutuzumab versus Ibrutinib and obinutuzumab in untreated younger patients with chronic lymphocytic leukemia (CLL).

We are writing to you today because we’ve noticed a difference in the reported COVID-19 related deaths between the treatment arms on this trial.

• As of 5/14/21, there are 3 reported deaths due to COVID-19 among the 381 participants randomized to the ibrutinib-obinutuzumab arm (Arm B) and 10 reported deaths due to COVID-19 among the 380 participants randomized to the ibrutinib-venetoclax-obinutuzumab arm (Arm A).

Other CLL trials using the same treatments used in EA9161 do not appear to be showing this difference. To better understand the reason for this finding in EA9161, we asked the independent Data Safety Monitoring Committee to evaluate all of the study data so that they could let us know should the study be stopped or otherwise changed in some way. The Committee met and evaluated the findings and recommended that the study continue as planned. The Committee wanted to make sure we remind all of the study participants that CLL is a high-risk factor for COVID-19.

Specifically, having CLL makes you at high risk for COVID-19. The Centers for Disease Control guidelines state that it is very important that you continue to take precautions for COVID-19. These preventive measures include wearing a mask and social distancing, as well as vaccination, which is recommended. Some vaccines may not work as well in those with CLL as they do in other people. We advise you not to rely solely on vaccination for protection. The new information that has come out stating that being around people outside of your home without wearing a mask does not apply to you because of your CLL.

Please consider this information carefully and discuss it with your study doctor. It is important that you seek immediate, expert medical care for COVID-19 if you experience any respiratory or other symptoms or suspect you may have the COVID-19 infection. If you develop COVID-19, it will be important to discuss the possible risks and benefits of your CLL treatment with your physician in deciding whether to continue protocol treatment after COVID diagnosis.

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 chronic lymphocytic leukemia. The Data Safety Monitoring Committee will be meeting every few months to look again at this finding. We will keep you notified should something change. We greatly appreciate your participation in EA9161.