

Update on the CALGB-100104 (Alliance) randomized trial

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Hello, my name is Dr. Philip McCarthy. I am from Roswell Park Cancer Institute in Buffalo, New York. I am here at ASCO 2017 to talk about a presentation we are giving which is an update of the CALGB-100104 randomized trial, examining lenalidomide versus placebo for maintenance therapy after single autologous stem cell transplant for multiple myeloma. The study was originally presented in 2012, and it was based on a progression-free survival endpoint. The study was unblinded originally in 2009 when that primary endpoint was met. At the time of the un-blinding, the patients who had not progressed on-study were allowed to crossover to receive lenalidomide if they had been receiving placebo. This crossover confounded future analyses because we now have placebo patients who are receiving lenalidomide. This analysis attempted to account for the crossover in the non-progressing patients, and there were two models that were used.

One is called a rank-preserving structural failure time model and the other one is an iterative parameter estimation. What these do is try and balance out the fact that you have placebo patients who receive study drug, and to account for them for a long-term analysis. What we were able to show was indeed the progression-free and overall survival benefit is preserved in this modeling, and if anything, it strengthens the PFS and OS because the patients who had crossed over are now not counted as strictly placebo patients. I think this is very gratifying. It also allowed me to learn about how you can account for crossover when you are using progression free survival as an early endpoint. We are looking forward to updates of the CALGB-100104 trial (now the Alliance trial). We have an update under revision, and there is a large meta-analysis that is going to be looking at a combination of the IFM-0502, CALGB-100104, and the GIMEMA RV-209 trial, all of which looked at lenalidomide maintenance; that also is under consideration for publication. Based on the recent FDA approval, lenalidomide maintenance is now considered a standard of care, and we continue to look at ways of better understanding the length of time for therapy and also which patients might benefit best from long-term maintenance therapy. I want to thank you very much for listening.