What are the latest updates in the Phase 3 study of gilteritinib and AZA vs AZA alone for ND FLT-3 AML in patients ineligible for induction chemotherapy?

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Welcome to *Managing AML*. I am Dr. Eunice Wang, and I am frequently asked, "Can you share some background on the study of gilteritinib and azacitidine versus azacitidine alone for newly diagnosed FLT3 mutant AML patients ineligible for induction chemotherapy? What was the significance of these results?"

These results were presented as part of the outcomes of the phase 3 LACEWING trial, a randomized trial for patients who had FLT3 mutant disease and were considered ineligible for induction chemotherapy, were randomized to receive gilteritinib and azacitidine versus azacitidine alone. There was no significant difference in overall survival between patients who received gilteritinib and azacitidine versus those that had azacitidine alone.

What is the significance of this? The significance of this, however, when you look a little bit deeper into the data, there was a much higher overall response rate in terms of CR, CRp, CRi, almost 50 percent in those patients that received gilteritinib and azacitidine, as opposed to much lower, 20-something percent in those that got azacitidine alone. In addition, subset analysis demonstrated a trend, not statistically significant, that patients who had FLT3-ITD mutant disease, particularly those with high allelic ratios, may have benefited from the addition of gilteritinib and azacitidine. Overall, the combination of gilteritinib and azacitidine was very well tolerated. Given the overall response rates of 50 percent with this particular regimen, this may be something that we're going to be exploring down the line, perhaps not in the upfront setting, but in combination approaches.

It must be remembered that this trial was hampered by a couple of problems. One of which was the fact that gilteritinib was approved during the conduct of the study, and the second of which there is no placebo control, so investigators may have been more likely to move patients on to additional therapy in the azacitidine arm alone. A majority of patients in that particular arm did go on to receive subsequent FLT3 therapy.

What does this help us with? This means that gilteritinib and azacitidine may be something that we're offering and particularly interested in potential triplet therapies of venetoclax, gilteritinib, and azacitidine, as opposed to doublet therapy with venetoclax and azacitidine or gilteritinib and azacitidine in this patient population. So more ahead building on this data to further optimize the treatments for these patients. Thank you very much for viewing this activity.