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What are the latest updates on the Beat AML Master Trial?

Welcome to *Managing AML*. I am Dr. Brian Druker. I am frequently asked to give an update on the Beat AML trial. I want to give a little bit of background about Beat AML and the master clinical trial sponsored by the Leukemia & Lymphoma Society. I think anybody who treats patients with AML knows the prognosis for AML is pretty dismal and has not changed in 30 to 40 years. We continue to use the same two-drug combination, daunorubicin with AraC, that we used 30 to 40 years ago, and there have been very few drugs approved for patients with AML in the past 3 to 4 decades. Despite that, we know an enormous amount about the genomics of AML. We know many of the common driving mutations, we know many of the cytogenetic subgroups, yet, we have not been able to act upon those. The premise behind the Beat AML master trial was to try to move treatment for patients with AML into the 21st century. The design is to enroll patients over 60 who were previously untreated, and do a full genomic profiling on those patients and turn that around in 7 days, then assign patients based on the genomics to various subsets. For example, patients in good prognostic subsets – NPM1 mutant patients or CBF where we know the chemotherapy benefits them – would get chemotherapy plus a novel agent. For patients with a poor prognosis – for example, FLT3 mutated patients or patients with IDH mutations or patients with a complex karyotype or p53 mutations - we know we need to use novel agents, particularly in the over-60 population.

The protocol was opened about 4 months ago at the end of November of 2016. We have enrolled 20 patients, and 19 of those 20 patients had their genomics turned around in 7 days so we can enroll the patients on the master trial. We currently have two arms open. One is CD200 targeting antibody, and the other is CD33 antibody. We will be opening additional arms including IDH1 and IDH2 arms. We will be opening a FLT3 mutated arm, adding a FLT3 inhibitor with novel agents, either azacitidine or in the future many other novel agents. The trial currently is open at Ohio State, Oregon Health Science University, Memorial Sloan Kettering, and will open very soon at Dana Farber, as well as five or six other centers. We are really excited about this clinical trial because we are hopeful that we are going to finally make an impact for patients with AML through the understanding that we have of the genomics and the driving mutations in patients with AML.

If a physician has a patient who is interested in this trial or they are interested in the trial, I would encourage you to go to the Leukemia & Lymphoma website, lls.org. There you will find quite a bit of information about the Beat AML clinical trial.