Now Enrolling: PrE0905 – Gilteritinib vs. Midostaurin for FLT3-Mutated Acute Myeloid Leukemia

Approximately one-third of patients with acute myeloid leukemia (AML) have a FLT3 mutation, and their relapse and survival rates are much worse than patients with AML whose leukemia cells don’t harbor this mutation. PrE0905, an open-label phase II study led by Selina Luger, MD (University of Pennsylvania), is exploring a new treatment approach for this group: the potent FLT3 inhibitor gilteritinib.

Untreated adult patients with FLT3 AML are eligible for this trial and enrollees will be randomized to receive gilteritinib or midostaurin during the induction and consolidation phases of treatment. Patients will also receive standard chemotherapy of daunorubicin and cytarabine during induction and high-dose cytarabine during consolidation. AML patients with known core binding factor and patients with acute promyelocytic leukemia (with or without a FLT3 mutation) are not eligible for this study.

In the last year, gilteritinib was approved for patients with relapsed/refractory FLT3-mutated AML, having demonstrated its effectiveness in improving survival as a single agent in this setting. The FLT3 inhibitor has not yet been approved in the upfront setting, and thus, Dr. Luger notes, PrE0905 is the only trial that will allow participating sites to potentially get gilteritinib added to induction therapy for AML.

Learn more about the trial on ClinicalTrials.gov. Dr. Luger also has recorded a brief, informational video for physicians and site staff that includes details on the patient screening process and procedures for submitting samples for FLT3 testing.

PrE0905 is currently open at approximately 20 sites across the US. Any site that is interested in participating should contact PrECOG.