

# MM1OA-EA02 Study

Do you have acute myeloid leukemia (AML) and are age 60 or older?

If so, you may be able to participate in this study of a potential new treatment.

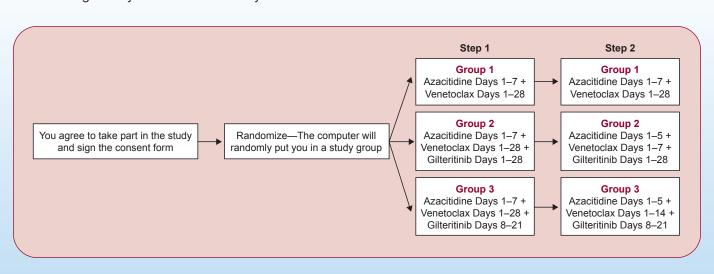
# Venetoclax and Hypomethylating Agent (HMA) Treatment of Older and Unfit Adults with FLT3 Mutated AML

### WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating cancer.
- The usual approach (i.e., the standard treatment most people get for AML) is treatment with chemotherapy and other drugs. Sometimes, combinations of these treatments are used.
- The purpose of MM1OA-EA02 is to compare the usual treatment of the drugs azacitidine and venetoclax to the combination treatment of azacitidine, venetoclax, and gilteritinib.
  - Researchers are trying to find out if adding the drug gilteritinib can lower the amount of leukemia in your body.

### WHAT does this study involve?

- This study is a part of the myeloMATCH Precision Medicine Trial, which you have previously agreed to participate in.
- If you are matched to the MM1OA-EA02 treatment study and choose to participate, you will be assigned by chance (randomized) to one of three study groups. Each study group will consist of approximately 49 participants.
  - Group 1: You will receive azacitidine (by injection into a vein in your arm or just beneath the skin) and venetoclax (a tablet you will take daily by mouth).
  - Group 2: You will receive azacitidine (via injection), venetoclax (via daily tablet), and gilteritinib (also a daily tablet you will take by mouth).
  - **Group 3:** You will receive azacitidine (via injection), venetoclax (via tablet), and the gilteritinib tablet, but starting on day 8 of the treatment cycle.



## MM1OA-EA02 Study

- Each cycle lasts 28 days and there will be a maximum of 24 cycles.
- After you finish MM1OA-EA02 study treatment, your doctor will monitor your condition for 10 years (every 3 months for the first 2 years, then every 6 months thereafter).

### WHO will take part in this study?

- Approximately 147 people diagnosed with AML will take part in MM1OA-EA02. You must be at least 60 years
  of age; however, individuals younger than 60 are eligible if your treating physician decides you would be better
  served by a treatment that includes azacitidine chemotherapy (instead of the more intensive cytarabine-based
  chemotherapy).
- You must also have a FLT3-ITD or D835 mutation, as required by the myeloMATCH Precision Medicine Trial.
- You can decide to stop taking part in this study at any time, even after you have enrolled.

### WHAT are the costs of taking part in this study?

- Just as if you were getting the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study.
  - You/your insurance plan will **not** have to pay for venetoclax and gilteritinib while you take part in MM1OA-EA02.
  - Check with your insurance company for find out what they will pay for.
- Taking part in the study may mean that you need to make more visits to the clinic or hospital than if you
  were getting the usual approach to treat your cancer.
- You will not be paid for taking part in MM1OA-EA02.

### **IF** you would like to know more

- About the MM1OA-EA02 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search MM1OA-EA02, then select the link to MM1OA-EA02.
    - » For information about medical facilities where the study is available, scroll down the page to Locations and Contacts.
    - » For more information on myeloMATCH, including a list of the myeloMATCH treatment trials, visit www.swog.org/myelomatch-overview.
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
- · About clinical trials:
  - General cancer information: visit the NCI website at www.cancer.gov
  - Insurance coverage: visit www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
  - Visit www.ecog-acrin.org
  - For a list of patient resources and links to patient advocacy groups, visit https://ecog-acrin.org/patients/resources



