SIERRA TRIAL

Novel Re-induction and Targeted Conditioning Therapy with **Iomab-B** [iodine (^{131}I) apamistamab] before transplant for patients 55 years or older with active, relapsed/refractory AML

Acute myeloid leukemia (AML) is typically a disease of older age with more than half of new cases diagnosed in patients 65 years of age and older.[1] Relapsed/refractory (R/R) AML in this population is difficult to treat and patients who have failed standard therapies in particular have a poor prognosis. Hematopoietic cell transplantation (HCT) is the only known curative treatment for these patients. Clinical trials, such as the SIERRA trial, are the preferred option.[2]

TREATMENT OPTIONS

Current NCCN Guidelines indicate that for patients with R/R AML, treatment options include:

- Clinical trial (strongly preferred)
- Chemotherapy and allogeneic HCT, only in a clinical trial or if remission is achieved
- Best supportive care
- Repeating induction regimen if late relapse[2]

The SIERRA trial is a new option for this population, testing the drug Iomab-B. The SIERRA trial is the only phase 3 trial that provides allogeneic HCT to older patients with R/R AML with active disease. The Food and Drug Administration (FDA) has not yet approved Iomab-B.

CLINICAL TRIAL

Title: Iomab-B Prior to HCT vs. Conventional Care in Older Subjects with Active, Relapsed or Refractory AML (NCT02665065)

Trial Type: Multicenter, randomized, open label, phase 3, crossover study

Goal: To find out if using Iomab-B before HCT is safe and works better for patients with R/R AML compared to conventional care

Patients may qualify if they:

- Are 55 years of age or older
- Have active, R/R AML
- Have a matched related or unrelated donor and plan to undergo first allogeneic HCT
- Have adequate organ function and blood counts as defined by the trial protocol

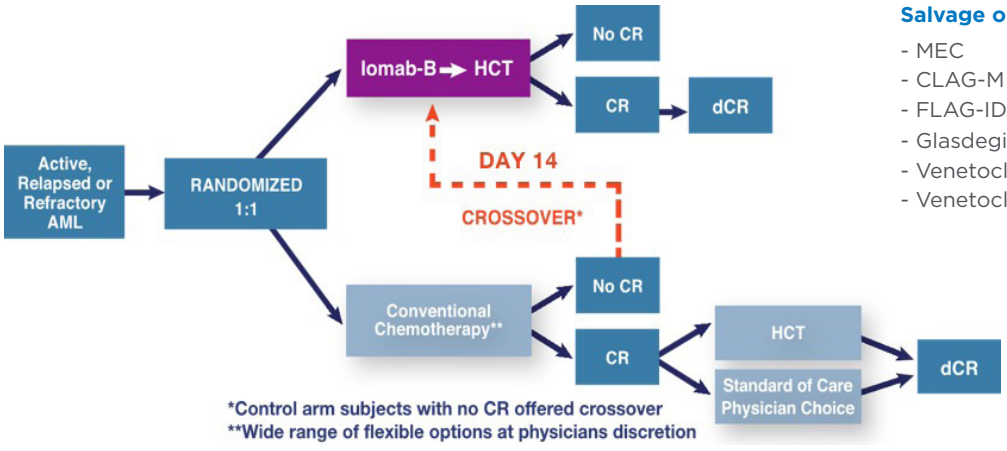
Treatments: Iomab-B is a radiolabeled anti-CD45 antibody. Patients are randomized 1:1 to either Iomab-B or conventional care.

Iomab-B arm

After Iomab-B administration, patients receive pre-HCT conditioning with fludarabine and total body irradiation.

Conventional care arm

Broad range of salvage chemotherapy options based on investigator's choice. If complete response (CR) is achieved, patients may proceed to standard of care/HCT. **If CR is not achieved, patients may crossover to Iomab-B arm and HCT as soon as day 14 (if progressive disease) without delay.**



Salvage options could include:

- MEC
- CLAG-M
- FLAG-IDA
- Gemtuzumab
- Enasidenib
- Gilteritinib
- Glasdegib + low-dose cytarabine
- Venetoclax + low-dose cytarabine
- Venetoclax + azacitidine or decitabine

References:

[1] Surveillance, Epidemiology, and End Results (SEER) Program Populations (1969-2016) (www.seer.cancer.gov/popdata), National Cancer Institute, DCCPS, Surveillance Research Program, released Dec 2017.

[2] National Comprehensive Cancer Network. Acute Myeloid Leukemia (3.2018). https://www.nccn.org/ professionals/physician_gls/pdf/aml.pdf. Accessed 12/11/2018.

Trial Locations

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