# For Patients with Acute Promyelocytic Leukemia

## EA9131 Available Through ECOG-ACRIN Cancer Research Group

*A Simplified Patient Care Strategy to Decrease Early Deaths in Acute Promyelocytic Leukemia (APL)*

### Patient Population

- All patients ≥ 18 years of age who are confirmed to have a diagnosis of APL, which is defined as:
  - Positive t(15;17) by FISH, or
  - Positive t(15;17) by conventional karyotype, or
  - Positive PML/RAR alpha by PCR

- Must accept treatment and supportive care guidelines

- Referrals must be made as early as possible by treating physician (provider) but no later than 3 calendar days after ATRA or APL directed therapy is initiated

- Consent can be obtained up until day 7 after initiating APL directed therapy

- Co-management can be started as soon as referral is made including weekends. The physician at the NCORP community facility should make every effort to call the APL expert at the first suspicion of APL

One NCORP site and five NCTN Sites will be referred to as the Lead Sites: Medical College of Georgia at Augusta University, Augusta, GA; Memorial Sloan Kettering Cancer Center, New York, NY; Mayo Clinic, Rochester, MN; Northwestern University, Chicago, IL; University of Pennsylvania, Philadelphia, PA and Mayo Clinic, Jacksonville, FL

**NOTE:** Other Academic sites will not participate in this trial. EA9131 will be restricted to the above-mentioned FIVE NCTN SITES and ALL NCORP COMMUNITY SITES.

### Treatment Plan

- **Lead Sites:**
  - 7 lead investigators accruing at 6 lead sites (Lead Sites) will serve as the APL experts
    - The APL expert will either manage the patient or provide consultative oversight to the treating team
    - The sub-investigators at the lead sites can consent patients but it is expected that the local PI will provide oversight
  - Patients treated at lead sites will be treated locally using treatment guidelines (Appendix I)

- **Outlying NCORP Community Facilities:**
  - The treating physician from the NCORP community facility should call the APL expert in their catchment area for treatment guidance
    - The call should be made as soon as APL is suspected but no later than 3 days after starting ATRA; communication should be ongoing based on the clinical developments until a hematologic remission is achieved
    - The provider at NCORP community centers will be the Hematologist/Oncologist attending caring for the patient; initial contact has to be made by a hematologist/oncologist, but trainees or advanced level practice providers can be in communication subsequently with APL experts to continue the care
  - A log will be maintained by the APL expert (Appendix II); subsequent calls/work decisions made will be documented on the log sheet; it is also suggested that the treating physician document communication on an ongoing basis
  - Study duration is 5 years: Accrual years 1—4 and follow-up for 1 year after accrual is completed

### Study Chair:

Anand P. Jillella, M.D.

### Co-Chair:

Vamsi K. Kota, M.D.

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**Patient Enrollment**

All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!
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