FAST FACTS

ALLIANCE A041701
A RANDOMIZED PHASE II/III STUDY OF CONVENTIONAL CHEMOTHERAPY +/- UPROLESELAN (GMI-1271) IN OLDER ADULTS WITH ACUTE MYELOID LEUKEMIA RECEIVING INTENSIVE INDUCTION CHEMOTHERAPY

Registration Eligibility Criteria (Step 1)

1. Documentation of Disease
   - Diagnosis of AML based on 2017 WHO criteria [22] excluding acute promyelocytic leukemia with PML-RARA. Note: Patients with myeloid sarcoma without bone marrow involvement, acute leukemia of ambiguous lineage or blast transformation of CML are not eligible.
   - No activating mutation in the Fms-like tyrosine kinase-3 (FLT3) defined as a ratio of mutant to wild-type allele ≥ 0.05 by capillary electrophoresis or a variant allele fraction of ≥ 5% by next generation sequencing from either bone marrow or peripheral blood.
   - No evidence of CNS involvement of AML

2. Prior Treatment
   - No prior chemotherapy for MDS, MPN, or AML including hypomethylating agents (e.g. azacitidine and decitabine), ruxolitinib or lenalidomide with the following exceptions:
     - Emergency leukapheresis
     - Hydroxyurea
     - Growth factor/cytokine support
     - All-trans retinoic acid (ATRA)
     - Single dose of intrathecal cytarabine and/or methotrexate for patients undergoing lumbar puncture to evaluate for CNS involvement

3. Age ≥ 60 years

4. Required Initial Laboratory Values
   - Total Bilirubin ≤ 3 x upper limit of normal (ULN)
   - Creatinine ≤ 3 x upper limit of normal (ULN)
   OR
   - Creatinine Clearance ≥ 30 mL/min/1.73m²
Schema

Arm 1

Remission Induction
Daunorubicin + Cytarabine

2nd Remission Induction (if required)
Daunorubicin + Cytarabine

CR/CRi

Consolidation (up to 3 cycles)
Cytarabine

Arm 2

Remission Induction
Uproleselan + Daunorubicin + Cytarabine

2nd Remission Induction (if required)
Uproleselan + Daunorubicin + Cytarabine

CR/CRi

Consolidation (up to 3 cycles)
Uproleselan + Cytarabine

† All patients must be pre-registered in order to submit the required bone marrow and peripheral blood specimens to the Alliance HEME Biorepository (see Sections 4.3 and 6.2).

* During Remission Induction, a bone marrow examination (aspirate and biopsy) on Day 14 (+3 days) is required in all patients. Patients with evidence of persistent leukemia on day 14 or a subsequent bone marrow biopsy will receive a second induction course (See Section 7.0). Patients who achieve either a CR or CRi are eligible to proceed to consolidation therapy.