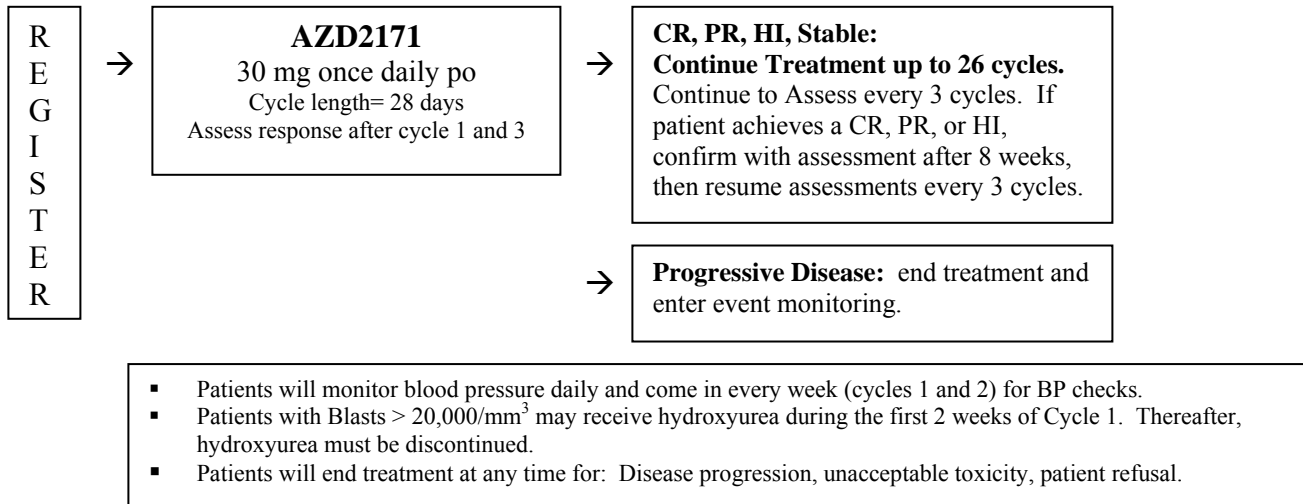


## MC048H: A Phase II Study of AZD2171 in Acute Myeloid Leukemia and Myelodysplastic Syndrome



### **MAJOR ELIGIBILITY CRITERIA:**

- Must have histologically confirmed AML (relapsed, resistant, or untreated) or MDS according to the WHO Classification.
  - Relapsed AML w/ Good risk cytogenetics (inv (16), t(8;21), or t(15;17)) in second or greater relapse or any other first or greater relapse Patients with AML t(15;17) must have failed ATRA and arsenic containing regimens prior to being eligible AND progressed or relapsed within 12 months of therapy.
  - Resistant AML: Any patient unable to achieve first CR after at least 2 induction regimens
  - Untreated AML: Any patient > 60 years of age,
  - Any patient with a preceding myelodysplastic syndrome
  - Myelodysplastic Syndrome (MDS): Any patient with an IPSS of intermediate-2 or higher as described on back of this sheet
- Age ≥ 18 years with an ECOG performance status of 0, 1, or 2.
- Total bili ≤ ULN, AST and/or ALT ≤ 2.5 x ULN, creatinine within normal institutional limits or creatinine clearance ≥ 60mL/min/1.73m<sup>2</sup>.
- Patients relapsing after allogeneic hematopoietic stem cell transplantation must be off all immunosuppressive medications for at least 30 days and have no signs/symptoms of GVHD.
- No chemotherapy, radiotherapy, or major surgery ≤ 4 weeks prior to registration.
- Not receiving any other investigational agents and has not participated in an investigational trial ≤ 30 days prior to registration.
- Has not received 4 or more courses of induction chemotherapy.
- Has not received growth factor or other cytokine support within 4 weeks of study entry.
- Not eligible for allogeneic HSCT (or those who have refused) at time of study entry.
- No active CNS leukemia, symptomatic leukostasis (or those requiring leukopheresis), or disseminated intravascular coagulation.
- No uncontrolled intercurrent illness; no known HIV.
- QTc < 500 msec (with Bazett's correction) in screening ECG and no history of familial long QT syndrome.
- LVEF > 45% - see back of sheet for screening.
- Does not have > +1 proteinuria on 2 consecutive urinalysis taken no less than 1 week apart
- Patient concurrent medications must be reviewed against protocol appendices VI, and VIII, those indicated as strong/prohibited must be discontinued with the washout period indicated – Appendices attached.

### **PRE-STUDY LABS AND TESTS:**

≤ 14 days prior to registration: EKG, ECHO

≤ 14 days prior to registration: CBC with diff, platelets, creatinine, total bili, AST, ALT, Alk Phos, Glucose, NA, K, BUN, TSH, free T4, troponin, urine alysis for protein, Bone marrow biopsy and aspirate;

Serum pregnancy test for woman of child bearing potential **within 7 days** prior to beginning treatment