

A Phase II Open-label Study of Olutasidenib Post-transplant Maintenance Therapy for Patients With IDH1-mutated Myeloid Malignancies

NCT06668584

Status	RECRUITING
Phase	Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	31 participants

Key Eligibility Criteria

Inclusion (21)

- Diagnosis of AML, MDS, MPN, or CMML according to World Health Organization (WHO) classification that underwent first or second alloSCT regardless of stem cell source, donor type/match, conditioning regimen, or GVHD prophylaxis and is at least 30 days post stem cell transplant until day 120.
- Evidence of an IDH1 mutation presence by next generation sequencing panel at original diagnosis.
- Evidence of engraftment by Absolute neutrophil count (ANC) $\geq 1.0 \times 10^9/L$ without daily use of myeloid growth factor (G-CSF) for at least 7 days; and Platelet $\geq 30 \times 10^9/L$ with out platelet transfusion within 1 week.
- Patient in morphologic remission with Day +30 bone marrow $<5\%$ blast. Will include MRD positive or negative.
- Age 18 to 75 years old.

... and 16 more (see full listing online)

Exclusion (11)

- Use of any of the following after transplantation and prior to starting study therapy. Anti-leukemic agents given as post-transplant maintenance therapy (e.g., subcutaneous, or oral 5-azacitidine or FL T3 inhibitors for maintenance)
- Overall grade II-IV aGVHD. However, upon complete resolution of aGVHD-related symptoms with grade 1 or 0 overall clinical grade would be appropriate to enroll at that time. Patients may be eligible for enrollment if they are on prednisone 0.5 mg/kg daily dose or lower, tacrolimus, sirolimus, and/or ruxolitinib.
- cGVHD, moderate or severe by NIH criteria.
- Active uncontrolled systemic fungal, bacterial, or viral infection. However, patients receiving anti-microbial agents including antibiotics, antiviral and antifungal therapies are allowed if the infection is controlled, and the patient is hemodynamically stable.
- Known active viral infection with Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).

... and 6 more (see full listing online)

Locations (1 total)

The University of Texas M. D. Anderson Cancer Center, Houston, Texas, United States

<https://clinicaltrials.gov/study/NCT06668584>

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