

Luspatercept for Clonal Cytopenias of Uncertain Significance

NCT06788691

Status	RECRUITING
Phase	Phase 2
Sponsor	Weill Medical College of Cornell University
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (22)

- Male or female \geq 18 years of age.
- Documentation of a CCUS diagnosis.
- Clonal cytopenia of undetermined significance (CCUS) is defined as clonal hematopoiesis of indeterminate potential (CHIP) detected in the presence of one or more persistent cytopenias that are otherwise unexplained by hematologic or non-hematologic conditions and that do not meet diagnostic criteria for defined myeloid neoplasms. Cytopenia definitions for diagnosis of CCUS include Hb $<$ 13 g/dL in males and $<$ 12 g/dL in females for anemia, absolute neutrophil count $<$ 1.8 \times 10⁹/L for leukopenia, and platelets $<$ 150 \times 10⁹/L for thrombocytopenia.
- Patients should harbor somatic mutations of myeloid malignancy-associated genes detected in the blood or bone marrow at a variant allele fraction (VAF) of \geq 2% (\geq 4% for X-linked gene mutations in males)
- Clinically significant cytopenias demonstrated in two separate lab draws and defined as cytopenia in any one of the following:
... and 17 more (see full listing online)

Exclusion (8)

- Concurrent malignancy requiring active concurrent systemic chemotherapy. Hormonal therapy for malignancy and targeted radiation is allowed. If patients after enrollment, have a clinical need for chemotherapy after achieving response on treatment, subjects deriving clinical benefit can be continued on study after discussion with study PI.
- Diagnosis of MDS, AML, MPN or any other myeloid malignancy in the patient's lifetime
- Active uncontrolled infection that in the investigators opinion will affect study procedures and/or results
- Active uncontrolled hypertension not responding to blood pressure lowering medications which in the investigator's opinion will be harmful for the patient.
- Use of ESA or growth factors within four weeks prior to the start of the study
... and 3 more (see full listing online)

Locations (1 total)

Weill Cornell Medical College, New York, New York, United States

<https://clinicaltrials.gov/study/NCT06788691>

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