Study of R289 in Patients With Lower-risk Myelodysplastic Syndromes (LR MDS)

NCT05308264

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Rigel Pharmaceuticals
Enrollment	86 participants

Key Eligibility Criteria

Inclusion (20)

- Patient must be e 18 years of age at the time of signing the informed consent.
- Must have definitive diagnosis of MDS with very low, low, or intermediate-1 risk (International Prognostic Scoring System (IPSS)-R d 3.5) and d5% bone marrow myeloblasts.
- Must be relapsed, refractory/resistant, intolerant, or have inadequate response to therapies with known clinical benefits for MDS, such as EPOs, luspatercept, and HMAs(i.e., azacytidine or decitabine). Patients with del (5q) must have failed prior lenalidomide therapy.
- DOSE ESCALATION PHASE:
- a. Must meet at least one of the following criteria prior to initial administration of study treatment: 1) Symptomatic anemia with hemoglobin \< 9.0 g/dL and no RBC transfusion within 16 of registration or 2) RBC transfusion dependent defined as receiving e 2 units of packed red blood cells (PRBCs) within 8 weeks in the preceding 16 weeks for a hemoglobin \<9.0 g/dL.

... and 15 more (see full listing online)

Exclusion (17)

- Prior treatment for MDS (i.e., TPOs, EPOs, luspatercept, HMAs) concluded \< 4 weeks prior to study treatment
- Clinically significant anemia resulting from iron, B12 or folate deficiencies, autoimmune or hereditary hemolysis, or GI bleeding.
- MDS secondary to treatment with radiotherapy, chemotherapy, and/or immunotherapy for malignant or autoimmune diseases.
- Diagnosis of chronic myelomonocytic leukemia.
- History of uncontrolled seizures.

... and 12 more (see full listing online)

Locations (15 total)

University of California, Los Angeles, Los Angeles, California, United States
University of California, Irvine, Orange, California, United States
Stanford Cancer Institute, Palo Alto, California, United States
... and 12 more locations

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