

ladademstat With Hypomethylating Agent in Patients With Myelodysplastic Syndrome

NCT06502145

Status	RECRUITING
Phase	Phase 1
Sponsor	Medical College of Wisconsin
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (21)

- Male or female 18 years or older.
- Patients must have a diagnosis of myelodysplastic syndrome (MDS), or MDS / myeloproliferative neoplasm (MPN), chronic myelomonocytic leukemia (CMML) as defined by the World Health Organization (WHO) criteria.
- Intermediate, high, or very-high risk by the Revised International Prognostic Scoring System (IPSS-R).
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 (0-3 if performance status is considered due to MDS).
- Patient must have a body weight of at least 50 kg.

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

Exclusion (16)

- Prior therapy with hypomethylating agent or Lysine-specific histone demethylase 1A (LSD1) inhibitor. If patients were treated with any other agents having KDM1A/LSD1 inhibitory activity (such as tranylcypromine or phenelzine or similar drugs), they are only allowed if treatment finalized at least 3 weeks prior to first dose on study.
- Patient will require treatment while on study with concomitant drugs that target the 5- hydroxytryptamine_{2B} (5-HT_{2B}) receptor or the sigma nonspecific receptor (e.g., escitalopram, fluoxetine, sertraline) except for drugs that are considered absolutely essential for the care of the patient and with appropriate treatment monitoring.
- Treatment with systemic antineoplastic chemotherapy within 14 days or 5 half-lives from the last dose - whichever is sooner - before Cycle 1, Day 1 of therapy. Radiation within 14 days before Cycle 1, Day 1 of therapy. The use of hydroxyurea for leukoreduction is permitted. Similarly, prior ESA, luspatacept, or lenalidomide is allowed. Subjects must have recovered from the side effects of prior therapy per the treating physician's discretion.
- Patient is on treatment with any investigational products within 3 weeks prior to the first dose of study treatment.
- Patient has had major surgery within 4 weeks prior to the first study dose.

... and 11 more (see full listing online)

Locations (1 total)

Froedtert Hospital & the Medical College of Wisconsin, Milwaukee, Wisconsin, United States

<https://clinicaltrials.gov/study/NCT06502145>

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