

A Randomized Study of ASTX727 With or Without Iadademstat in Advanced Myeloproliferative Neoplasms (MPNs)

NCT06661915

Status	RECRUITING
Phase	Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	62 participants

Key Eligibility Criteria

Inclusion (19)

- Patients must have morphologically confirmed diagnosis of Philadelphia-chromosome negative MPN in accelerated-phase (10-19% myeloid blasts) or blast-phase (≥ 20% myeloid blasts) arising from polycythemia vera, essential thrombocythemia, primary myelofibrosis, secondary myelofibrosis, or MPN not otherwise specified, as per the World Health Organization (WHO) 2016 classification OR myelodysplastic syndrome (MDS)/MPN overlap syndromes (e.g., chronic myelomonocytic leukemia [CMML]) with ≥ 10% blasts
 - Patients must not have received prior DNMTi. Previous use of janus kinase (JAK) inhibition, hydroxyurea, and interferon is allowed. There is no required washout period
 - Age ≥ 18 years
 - Because no dosing or adverse event data are currently available on the use of ASTX727 (35 mg decitabine + 100 mg cedazuridine) in combination with iadademstat in patients < 18 years of age, children are excluded from this study
 - Eastern Cooperative Oncology Group (ECOG) performance status ≤ 3 (Karnofsky ≥ 30)
- ... and 14 more (see full listing online)

Exclusion (11)

- Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities ≥ grade 1) with the exception of alopecia
 - Patients who are receiving any other investigational agents or had received any investigational products within 3 weeks or 5 half-lives (whichever is shorter) prior to first dose of study treatment
 - Patients with a Fridericia's corrected QT interval (QTcF) ≥ 450 ms
 - History of allergic reactions attributed to compounds of similar chemical or biologic composition to ASTX727 (35 mg decitabine + 100 mg cedazuridine) or iadademstat
 - Patients medicated with anti-depressants reported to have KDM1A/LSD1 inhibitory activity: tranylcypromine or phenelzine
- ... and 6 more (see full listing online)

Locations (26 total)

UCI Health - Chao Family Comprehensive Cancer Center and Ambulatory Care, Irvine, California, United States
UC Irvine Health/Chao Family Comprehensive Cancer Center, Orange, California, United States
UM Sylvester Comprehensive Cancer Center at Coral Gables, Coral Gables, Florida, United States
... and 23 more locations

<https://clinicaltrials.gov/study/NCT06661915>

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