

Study on Efficacy and Safety of Givinostat Versus Hydroxyurea in Patients With Polycythemia Vera

NCT06093672

Status	RECRUITING
Phase	Phase 3
Sponsor	Italfarmaco
Enrollment	220 participants

Key Eligibility Criteria

Inclusion (13)

- Patients must have been diagnosed with PV according to the 2016 WHO criteria before randomization
- Patients must have JAK2V617F-positive disease
- Patients with PV must meet the definition of HR for thrombosis (i.e., HR) within 3 years before screening as follows:
- Age \geq 60 years, and/or
- Prior thrombosis.

... and 8 more (see full listing online)

Exclusion (16)

- Patients pre-treated with HU with a documented history of resistance or intolerance to HU defined by the original ELN criteria
- Patients with a QTcF value of $>$ 450 msec for males and $>$ 460 msec for females at the Screening visit (as the mean of 3 consecutive readings 5 minutes apart in the event a first ECG demonstrates a prolonged QTcF interval); congenital or acquired history of QTc prolongation or ventricular arrhythmias, at the Screening visit
- Splanchnic thrombosis and/or thrombosis of the cerebral venous sinuses and/or splenectomy in the medical history
- Patients with clinically significant cardiovascular disease
- Patients with myocardial infarction, stroke or unstable angina within the 6 months prior to screening.

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

Locations (90 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Emad Ibrahim, MD, Inc, Redlands, California, United States
US Oncology Inc, Englewood, Colorado, United States
... and 87 more locations