Evaluation of HU-resistance in Adult Patients With Polycythemia Vera Who Meet PV-AIM Predictors

Last Update: Apr 16, 2025
HU-F-AIM - A Prospective, Interventional Study to Evaluate HU-resistance in Polycythemia Vera Patients Who Meet Predictive Parameters Identified in the Machine Learning Project PV-AIM
ClinicalTrials.gov Identifier:
NCT05853458
Novartis Reference Number:CINC424BDE15
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to confirm the predictive factors for hydroxyurea (HU) failure (hemoglobin (HGB) \ <15.5 g/dL (9.62 mmol/L) and red blood cell distribution width (RDW) ≥17%) identified by machine learning in the polycythemia vera advanced integrated model (PV-AIM) project in the real-life setting. The study consists of three periods: Screening period, treatment period (observation for HU-resistance/intolerance) and follow-up (FU) period.

Eligible participants will enter the treatment period (observation period for HU-resistance/intolerance) and start receiving the de novo HU treatment. The maximum treatment duration for each participant in the study will be up to 15 months.

This study will be conducted in a total of 300 adult PV patients and approximately at 30 to 40 sites in Germany. If necessary, the study will be extended to other countries to achieve the target population.

Condition
Polycythemia Vera
Phase
Phase4
Overall Status
Recruiting
Number of Participants
300
Start Date
Jul 28, 2023
Completion Date
Jan 27, 2027
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Drug

Hydroxyurea

Hydroxyurea is commercially available in Germany and will be prescribed based on clinical judgment

Eligibility Criteria

Key Inclusion criteria

1. Signed informed consent must be obtained prior to participation in the study
2. Patients ≥18 years
3. Confirmed diagnosis of Polycythemia vera (according to WHO 2008, 2016, or 2022 criteria) (Tefferi and Vardiman 2008, Arber et al 2016, Khoury et al 2022)
4. Eastern Cooperative Oncology Group (ECOG) ≤ 2
5. No previous pharmacologic cytoreductive therapy (including investigational drugs)
6. No phlebotomy in last 14 days
7. HU-eligible

* High-risk: age ≥ 60 years and/or prior history of thrombosis
* Low-risk: showing at least one of the defined criteria

* Signs of disease progression (myeloproliferation):

* Increase in spleen size or symptomatic splenomegaly
* Platelet increase to \> 1,000,000/µl
* WBC increase to \> 15,000/µl or higher
* Frequent (\> 10 per year) or increasing frequency of phlebotomies
* Increasing risk of thromboembolism and bleeding:

* New thromboembolism and/or hemorrhagic complications
* Microcirculation disorders despite acetyl salicylic acid (ASA) 2x 100 mg/day
* Restricted feasibility or intolerance of phlebotomies
* Symptomatic iron deficiency
* Uncontrolled increase in hematocrit
* Severe or distressing disease-related symptoms
8. Female participants of childbearing potential should have a negative serum pregnancy test within 72 hours prior to receiving the first dose of study treatment.

Key Exclusion criteria

1. Patients with post-polycythemia vera myelofibrosis (post-PV MF) or accelerated phase/ blast phase myeloproliferative neoplasm acute myeloid leukemia (AP/BP-MPN AML).
2. Patients with a contraindication to HU according to the SmPC (severe bone marrow depression, leukopenia (\< 2.5 x 109 leukocytes/l), thrombocytopenia (\< 100 x 109 platelets/L), severe anemia (\< 10 g/dL HGB).
3. Patients with rare hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption in their past medical history.

4. Active uncontrolled infection that is considered by the Investigator as a reason for exclusion.
5. Active malignancies (except for carcinoma in situ; prostate cancer and breast cancer in remission and - where necessary - ongoing hormonal therapy).
6. Inadequate renal function as demonstrated by Modification of Diet in Renal Disease estimate glomerular filtration rate (MDRDeGFR) \< 30 mL/min/1.73m2 or on dialysis.
7. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive human chorionic gonadotrophin (hCG) laboratory test.
8. Sexually active males unwilling to use a condom during intercourse while taking study treatment and for at least 3 months after stopping study treatment.
9. HIV patients treated with nucleoside reverse transcriptase inhibitors like didanosine and stavudine.

Other inclusion/exclusion criteria may apply

Germany

Novartis Investigative Site

Recruiting

Erfurt,99085,Germany

Novartis Investigative Site

Recruiting

Guetersloh,33332,Germany

Novartis Investigative Site

Recruiting

Augsburg,86150,Germany

Novartis Investigative Site

Recruiting

Mutlangen,73557,Germany

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Recruiting

Heidelberg,Baden Wuerttemberg,69115,Germany

Novartis Investigative Site

Recruiting

Gera,07548,Germany

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Recruiting

Goslar,Niedersachsen,38642,Germany

Novartis Investigative Site

Recruiting

Berlin,10407,Germany

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Recruiting

Naunhof,04683,Germany

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Straubing,Bayern,94315,Germany

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Hannover,30161,Germany

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Halle Saale,Sachsen-Anhalt,06110,Germany

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Bonn,53113,Germany

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Recruiting

Saarbruecken,66113,Germany

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Recruiting

Langen,Hessen,63225,Germany

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Recruiting

Kiel,24105,Germany

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Recruiting

Kronach,Bayern,96317,Germany

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Recruiting

Donauwoerth,86609,Germany

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