Dose Optimization and Expansion Study of DFV890 in Adult Patients With Myeloid Diseases

Last Update: May 28, 2025
A Phase 1b, Open Label, Multi-center, Dose Optimization and Dose Expansion Study to Assess the Safety and Efficacy of DFV890 in Adult Patients With Myeloid Diseases
ClinicalTrials.gov Identifier:
NCT05552469
Novartis Reference Number:CDFV890G12101
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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

Study CDFV890G12101 is an open-label, phase 1b, multicenter study with a randomized two-dose optimization part, and a dose expansion part consisting of two groups evaluating DFV890 in patients with myeloid diseases. The purpose of this study is to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, efficacy and recommended dose for single agent DFV890 in patients with lower risk (LR: very low, low or intermediate risk) myelodysplastic syndromes (LR MDS) and lower risk chronic myelomonocytic leukemia (LR CMML). This research study is to find out if study treatment DFV890 is safe and tolerable, and can help patients who were diagnosed with a myeloid disease such as: very low, low or intermediate risk myelodysplastic syndromes (MDS) and very low, low or intermediate risk chronic myelomonocytic leukemia (CMML). The study seeks to determine the optimal dose of DFV890 that is safe and efficacious in patients with myeloid disease. The effectiveness and safety/tolerability of the study treatment is not yet confirmed in this disease setting.

Eligible patients meeting all study entry requirements will be required to provide a sample from their bone marrow at screening and at select study timepoints. All enrolled patients will be dosed for a minimum of twenty-four weeks (6 cycles of treatment) unless they experience side effects related to the study treatment requiring dose interruption/discontinuation, worsening of the disease, and/or if treatment is discontinued at the discretion of the investigator or the patient.

Condition
Myeloid Diseases
Phase
Phase1
Overall Status
Recruiting
Number of Participants
80
Start Date
May 08, 2023

Completion Date
Feb 01, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

DFV890

DFV890 Single Agent

Eligibility Criteria

Key Inclusion Criteria:

1. Patients must be ≥ 18 years of age at the time of signing the informed consent form (ICF)
2. The Eastern Cooperative Oncology Group (ECOG) performance status (PS) ≤ 2
3. Patient must be a candidate for serial bone marrow aspirate and/or biopsy according to the institutions guidelines and must be willing to undergo a bone marrow aspirate.
4. Patients must have one of the following for eligibility into the study:

1. In dose optimization and expansion: IPSS-R defined very low, low or intermediate risk Myelodysplastic Syndrome (LR MDS) who failed to respond to or did not tolerate ESAs or luspatercept or HMAs and patients with del 5q who failed to respond to or did not tolerate lenalidomide; or
2. In dose optimization and expansion: IPSS-R defined very low, low or intermediate risk Chronic Myelomonocytic Leukemia (LR CMML) who failed to respond to or did not tolerate hydroxyurea or HMAs.

Key Exclusion Criteria:

1. Systemic antineoplastic therapy (including cytotoxic chemotherapy, alpha-interferon, kinase inhibitors or other targeted small molecules, and toxin-immunoconjugates) or any experimental therapy within 28 days or 5 half-lives, whichever is longer, and recovered from the toxicities before the first dose of study treatment. For patients that received antibodies the washout period is 4 weeks prior to study treatment.
2. History of hypersensitivity to the study treatment or its excipients or to drugs of similar chemical classes.
3. Patients who have previously been treated with agents that have the same mechanism of action as DFV890 as defined in Table 6-8, list of prohibited medications (e.g., drugs targeting the NLRP3 inflammasome pathway and the IL-1 pathway (canakinumab and anakinra)).
4. Use of hematopoietic colony-stimulating growth factors (e.g., G-CSF, GM-CSF, M-CSF), thrombopoietin mimetics or erythroid stimulating agents anytime ≤ 1 week (or 5 half lives, whichever is longer) prior to start of study treatment.
5. Patients receiving:

1. concomitant medications that are known to be modulators of cytochrome P450 enzymes CYP2C9 and/or CYP3A (specifically strong or moderate inducers of CYP2C9, strong inducers of CYP3A enzymes, strong inhibitors of CYP2C9 and/or strong or moderate dual inhibitors of CYP2C9/CYP3A); and
2. patients, who are poor CYP2C9 metabolizers receiving concomitant medications known to be strong or

moderate inhibitors of CYP3A, whose concomitant medications cannot be discontinued or switched to a different medication within 5 half-lives or 1 week (whichever is longer) prior to start of study treatment and for duration of the study. See Section 6.8 and list of prohibited drugs in Appendix 8 for more details.

Other protocol-defined inclusion/exclusion criteria may apply.

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