Study of PIT565 in Relapsed and/or Refractory B-cell Malignancies

Last Update: Jun 03, 2025
A Phase I, Open-label, Multi-center Study of PIT565 in Patients With Relapsed and/or Refractory B-cell Malignancies
ClinicalTrials.gov Identifier:
NCT05397496
Novartis Reference Number:CPIT565A12101
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

This is an open-label, multicenter, phase I study, which primary objective is to characterize the safety and tolerability of PIT565 and to identify maximal tolerated doses (MTDs) and/or recommended doses (RDs), schedule and route of administration in relapsed and/or refractory B-cell Non-Hodgkin lymphoma (R/R B-NHL) and relapsed and/or refractory B-cell acute lymphoblastic leukemia (R/R B-ALL). This is an open-label, multicenter, phase I study of PIT565 in patients with R/R B-NHL and R/R B-ALL.

The study comprises a dose escalation part of PIT565 in two independent groups (group A: R/R B-NHL and B: R/R B-ALL) and a dose expansion part in three independent groups (R/R large B-cell lymphoma (LBCL) randomized in 1:1 ratio to two RDs (A1 and A2), and R/R B-ALL (B1)).

During the dose escalation, the safety (including the dose-dose limiting toxicity (DLT) relationship) and tolerability of PIT565 will be assessed, and schedule(s), route(s) of administration and dose(s) will be identified for use in the expansion part based on the review of these data. The RD will also be guided by the available information on pharmacokinetics (PK), pharmacodynamics (PD), and preliminary anti-tumor activity. The dose escalation will be guided by an adaptive Bayesian logistic regression model (BLRM) following the Escalation with Overdose Control (EWOC) principle.

Different schedules and routes of administrations will be explored in the dose escalation groups.

The dose expansion will further explore the MTD(s) and/or RD(s) and the selected schedule(s) and route of administration(s) in the three patients' groups.

Condition
B-cell Non-Hodgkin Lymphoma (B-NHL), B-cell Acute Lymphoblastic Leukemia (B-ALL)
Phase
Phase1
Overall Status
Recruiting
Number of Participants

140
Start Date
Oct 03, 2022
Completion Date
Jun 05, 2028
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Biological

PIT565

Intravenous (i.v.) infusion or Subcutaneous (s.c.) injection

Eligibility Criteria

Inclusion Criteria:

* Signed informed consent must be obtained prior to participation in the study.
* Male or female patients ≥18 years of age at the date of signing the informed consent form
* Eastern Cooperative Oncology Group (ECOG) performance status ≤2

NHL patient population

* Refractory or relapsed B-NHL
* Must have relapsed after or failed to respond to at least two prior treatment therapies including an αCD20 monoclonal antibody containing chemotherapy combination regimen
* Must have at least one bi-dimensionally measurable nodal lesion or one bi-dimensionally measurable extranodal lesion, as measured on positron emission tomography-computed tomography (PET/CT) scan

ALL patient population

* Refractory or relapsed CD19-positive B-ALL
* Morphologic disease in the bone marrow (≥ 5% blasts)

Exclusion Criteria:

* History of severe hypersensitivity to any ingredient of the study treatment or its excipients
* Contraindication to tocilizumab
* History of ongoing, chronic or recurrent infectious disease, or evidence of tuberculosis infection
* Malignant disease, other than that being treated in this study. Exceptions to this exclusion include the following: malignancies that were treated curatively and have not recurred within 2 years prior to study treatment; completely resected basal cell and squamous cell skin cancers, and completely resected carcinoma in situ of any type
* Active central nervous system (CNS) involvement by malignancy or presence of symptomatic CNS metastases, or CNS metastases that require local CNS-directed therapy (such as radiotherapy or surgery), or increasing doses of corticosteroids within the 2 weeks prior to the start of study treatment

* Active, known or suspected autoimmune disease other than patients with vitiligo, residual hypothyroidism only requiring hormone replacement, psoriasis not requiring systemic treatment or conditions not expected to recur
* Patients receiving systemic treatment with any immunosuppressive medication

Other protocol-defined inclusion/exclusion criteria may apply.

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