ARV-393-101

ARV-393

NOW ENROLLING

A Phase 1 First-in-Human Study of ARV-393 in Patients With Relapsed/Refractory Non-Hodgkin Lymphoma

ARV-393 is an investigational compound and is not approved for any use. Its safety and effectiveness have not been established.

Trial Schema

Patients with relapsed/refractory B-cell NHL or nTFHL-AI (including AITL)

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Dose escalation to assess safety and tolerability of oral ARV-393

Key Eligibility Criteria[a]

Inclusion Criteria

- Men and women aged ≥18 years
- Relapsed/refractory mature B-cell NHL or histologically confirmed nTFHL-AI that has recurred or progressed
  - ≥2 lines of prior therapy for patients with relapsed/refractory mature B-cell NHL
  - Progression or disease recurrence following standard of care therapy for patients with nTFHL-AI
- ≥1 measurable lesion at study entry
- ECOG performance status of 0 or 1
- Freshly biopsied or archival tumor tissue available

Exclusion Criteria

- Prior allogeneic stem cell transplant
- Significant acute or chronic medical illness, including hypereosinophilic syndrome, active interstitial lung disease or pneumonitis, or active or uncontrolled infection

Summary of Outcome Measures

Primary Endpoints

- DLTs
- Safety and tolerability

Secondary Endpoints

- Pharmacokinetic parameters of ARV-393
- ORR,[b] CRR,[c] and DOR

[a]This is not the complete list of inclusion/exclusion criteria.
[b]The proportion of participants achieving a complete response or partial response according to the Lugano response criteria for NHL.
[c]The proportion of participants achieving a complete response according to the Lugano response criteria for NHL.

AE=adverse event; AITL=angioimmunoblastic T-cell lymphoma; CRR=complete response rate; DLT=dose-limiting toxicity; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; NHL=non-Hodgkin lymphoma; nTFHL-AI=nodal T-follicular helper cell lymphoma, angioimmunoblastic-type; ORR=objective response rate.

This information is current as of November 2024.

For additional protocol details, please visit www.ClinicalTrials.gov (NCT06393738)

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