Phase 1 study protocol: NKTR-255 as monotherapy or combined with daratumumab or rituximab in hematologic malignancies

Authors

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Trial registration number

NCT04136756

Study Outcomes

Primary outcomes

Dose-escalation phase: safety and tolerability, MTD and RP2D of NKTR-255 monotherapy

Dose-expansion phase: safety and tolerability of:

- NKTR-255 monotherapy in patients who have progressed on a CAR-T therapy with relapsed/refractory MM, NHL or iNHL
- NKTR-255 plus daratumumab in patients with relapsed/refractory MM
- NKTR-255 plus rituximab in patients with relapsed/refractory iNHL

Secondary key outcomes

ORR, PK, and PD of NKTR-255 monotherapy and in combination with daratumumab or rituximab

Key Eligibility Criteria

- ≥18: Aged ≥18 years
- Relapsed/refractory MM or NHL with progressive disease on/after their last regimen
- ECOG PS ≤ 2
- Response to at least 1 prior line of treatment
- All patients who received prior investigational CAR-T are eligible after confirmation of relapse of their primary disease
- Patients with MM: measurable disease (defined by the IMWG criteria) with ≥ 3 prior lines of therapy with no other available treatment options
- Patients with NHL or iNHL: histologically confirmed CD19-/CD20-positive disease

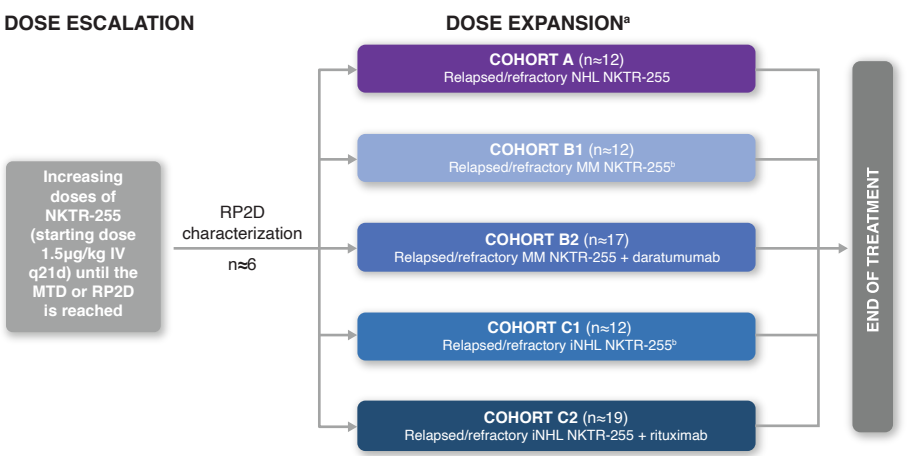
Study Design and Treatment

P1 Phase 1

Open label

Multicenter

Dose escalation (n≈46)
Dose expansion (n≈72)



[a]During dose expansion patients will be treated with NKTR-255 at the RP2D at either every 21- or 28-day dosing schedule

[b]Patients in Cohorts B1 and C1 who fail to respond to treatment are permitted to cross over to the combination Cohorts B2 and C2, respectively, after at least one disease assessment

Glossary

CAR-T: Chimeric antigen receptor T cell; ECOG PS: Eastern Cooperative Oncology Group Performance Status; IMWG: International Myeloma Working Group; iNHL: Indolent non-Hodgkin lymphoma; IV: Intravenously; MM: Multiple myeloma; MTD: Maximum tolerated dose; NHL: Non-Hodgkin lymphoma; ORR: Objective response rate; PD: Pharmacodynamics; PK: Pharmacokinetics; q21d: Every 21 days; RP2D: Recommended Phase 2 dose

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