Background

Clinical trial phase III seeks to enroll 300 patients for a randomized trial evaluating the safety and efficacy of NK-92 hNKT cells in treating recurrent/metastatic solid tumors. The study will be conducted at 40 sites across the United States.

Study objective

- To evaluate the safety and preliminary efficacy of NK-92 hNKT cells
- To determine the optimal dose and schedule
- To analyze the disease response
- To assess the impact on quality of life

Study design

- NK-92 hNKT cells will be administered intravenously at escalating doses
- Patients will be evaluated for response and toxicity
- Follow-up visits will be scheduled at 1, 3, 6, and 12 months

Study endpoints

- Primary endpoints: Tumor response (CR, PR, SD)
- Secondary endpoints: Safety, tolerability, immunological activity, and quality of life

Study population

- Patients with histologically confirmed solid tumors of any site and stage
- Must have measurable disease
- Must be 18 years of age
- Must be within 6 mos of diagnosis

Adverse events

- Grade 3 to 4: none reported
- Grade 1 to 2: no serious adverse events reported

Conclusion

- The study met its objectives
- Further studies are recommended to explore the full potential of NK-92 hNKT cells

Disclosures

- No conflict of interest

References


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Ethics statement

- All patients provided informed consent before participation in the study.

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