Doctor's Note — Clinical Trial Summary

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TRIAL

Study Assessing MTD, Safety, Tolerability, PK and Anti-tumor Effects of LNS8801alone and With Pembrolizumab

NCT ID: NCT04130516 Phase: PHASE1 / PHASE2 Sponsor: Linnaeus Therapeutics, Inc. Status: Active Not Recruiting

SUMMARY

This Phase 1/2, first-in-human, open-label, multicenter study follows a 3+3 ascending dose escalation design to determine the MTD/RP2D and to characterize the safety, tolerability, PK, and antitumor effects of LNS8801 alone and in combination with pembrolizumab. The study will include a dose escalation phase, a dose expansion phase, and phase 2A cohorts. Up to 200 patients will be accrued for this study. Up to 15 study sites in the United States will participate in the study.

KEY ELIGIBILITY CRITERIA

- Prescreening Inclusion Criteria for genotyping:
- 1. Has histopathologically confirmed locally advanced or metastatic solid tumor cancer.
- 2. Is able to understand and voluntarily sign a written informed consent form and is willing and able to comply with protocol requirements.
- 3. Is considered likely to meet the detailed inclusion and exclusion criteria for treatment when required.
- 1. Has histopathologically confirmed locally advanced or metastatic solid tumor cancer (or lymphoma in Phase 1). The solid tumor cancer is further defined in some cohorts as:
- 1. Phase 1B monotherapy expansion cohort:
- Has melanoma, except uveal melanoma, and has previously received anti-PD-1/L1 therapy and is now not eligible for anti-PD-1 treatment in the judgement of the Investigator due to prior severe immune related adverse events, and has not received intervening cancer therapy since the anti-PD-1/L1 therapy.
- 2. Monotherapy Cohort M2:
- Has pancreatic, gastric, non small cell lung cancer (NSCLC), or colorectal cancer.
- 3. Monotherapy Cohort M3:

Total sites: 10 | 0 currently recruiting

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