Doctor's Note — Clinical Trial Summary

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TRIAL

Study of LVGN3616 and LVGN6051±LVGN7409 in Combination With Nab-Paclitaxel or Bevacizumab and Cyclophosphamide in Metastatic Solid Tumors

NCT ID: NCT05075993 Phase: PHASE1 Sponsor: M.D. Anderson Cancer Center Status: Terminated

SUMMARY

This is an investigator-initiated industry-supported phase 1 clinical trial conducted in the phase 1 clinic at The University of Texas MD Anderson Cancer Center who will hold the Investigational New Drug (IND). Lvygen Biopharma will provide as investigational supply LVGN3616, LVGN6051 and LVGN7409 at no cost to the patients on this study. This study will explore antitumor activity of four LVGN3616 and LVGN6051 based regimens in seven selected tumor types:

KEY ELIGIBILITY CRITERIA

- To be eligible for this trial, patients must meet all the following eligibility criteria.
- * Patients must have histologically confirmed metastatic solid tumors with pre-identified molecular profiling in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, either refractory to standard therapy or for which no effective standard therapy that increases survival for at least 3 months is available, or they declined standard of care therapy (the treating physician needs document reasons for a patient to decline standard of care therapy and provide justification for participating this study in the medical record, which will be recorded in eCRF).
- * Measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1.
- * Male or female aged e18 years.
- * Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
- * Adequate organ functions as defined below:
- * Absolute neutrophil count (ANC) e 1,500¼
- * Hemoglobin (Hb) e 8.5 g/dL.
- * Platelets e 100,000¼for nab-paclitaxel or e 75,000¼for cyclophosphamide.
- * Total bilirubin d 1.5 × upper limit of normal (ULN); or total bilirubin \< 3.0 × ULN with direct bilirubin d ULN in patients with well documented Gilbert's Syndrome.

Total sites: 1 | 0 currently recruiting

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