A First-in-Human Phase 1 Dose-escalating Trial of G305 in Patients with Solid Tumors Expressing NY-ESO-1

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I. BACKGROUND

A major way to respond to ongoing antitumor immune surveillance, evasion, and failure is to generate antigen-specific CD8 T cells that target solid tumors.

Methods: Adults with metastatic melanoma or sarcoma, primary breast, ovarian, or renal cancer expressing NY-ESO-1 were enrolled in a first-in-human study. Participants were randomized 2:1 to LV305 alone or LV305/G305. Safety, immunogenicity, and clinical responses were assessed prior to, during, and at the end of therapy.

Indication: Adults with metastatic melanoma, sarcoma, breast, ovarian, or renal cancer expressing NY-ESO-1 will be treated desensitized (day-9) with LV305 and re-challenged weekly with G305 until disease progression.

Conclusion: Clinical trials are ongoing to evaluate the potential of NY-ESO-1-specific CD8 T cell therapy in melanoma, sarcoma, and other cancers expressing NY-ESO-1.

G305 Induced Significant Antibody and CD4 T-cell Responses

Dose-escalation Cohorts had Similar Tumor Types and Disease Status

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