Liminatus Pharma LLC

GCC Cancer Vaccine

Phase II Trial Design

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Ad5.F35-hGCC-PADRE is an adenovirus vector based on non-replicable Ad5 that has been modified through recombination. Ad5.F35-hGCC-PADRE expresses both the extracellular domain of human guanylate cyclase C (GCC1-430) as well as the unique synthetic CD4+ T-cell epitope called PADRE. This modified vector has replaced Ad5's fiber molecule with that of Ad35 virus in order to improve vector tolerance against the existing Ad5-specific immunity. Ad5.F35-hGCC-PADRE is designed for the treatment of gastrointestinal adenocarcinoma (esophagus, pancreas, stomach, and large intestine) patients with GCC expression. Phase 2 clinical trial design is as follows.

Name of Sponsor: Thomas Jefferson University

Name of Investigational Product: Ad5.F35-hGCC-PADRE

Name of Active Ingredient: Guanylyl Cyclase C (GCC)-Encoding Replication Deficient Human Type 5 Recombinant Adenovirus Vaccine

Title of Study: A Phase 2A, Dose-Finding Study of Ad5.F35-hGCC-PADRE Vaccine in Adults with Gastrointestinal Adenocarcinomas at Risk of Relapse Post Definitive Surgery and Standard Therapy

Short Title: Phase 2A Study of Ad5.F35-hGCC-PADRE in Gastrointestinal Malignancies

Study Center(s): Thomas Jefferson University

Principal Investigator: Babar Bashir, M.D.

Co-Investigators: Scott A. Waldman, M.D., Ph.D., Adam E. Snook, Ph.D., Scott Goldstein, M.D., Jonathan R. Brody, Ph.D., Takami Sato, M.D., Ph.D., James A. Posey, M.D., Walter K. Kraft, M.D.

Studied Period (years): Estimated date first patient enrolled: 10/01/19,
Estimated date last patient completed: 12/01/21

Phase of Development: Phase 2A

Study Rationale: This is an open-label, dose-finding, Phase 2A study of Ad5.F35-hGCC-PADRE as a vaccine for gastrointestinal (GI) malignancies (pancreatic, colorectal, esophageal, and gastric adenocarcinomas) who have received surgical resection and standard adjuvant therapy. Patients will be given multiple administrations of Ad5.F35-hGCC-PADRE intramuscularly at 1 of 3 dose levels. Treatment-related toxicity and development of immune responses to GCC will be evaluated at weeks 5, 9, and 13 after the initial vaccination (week 1). Primary safety end-points will examine adverse events (AEs), injection site reactions and clinically significant changes in safety laboratory tests. Primary efficacy endpoints include the development of GCC-specific T-cell responses at different dose levels (10^{11}, 10^{12}, and $5x10^{12}$ virus particles or vp).

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Primary Objectives:

1) Evaluate the safety and tolerability of sequential Ad5.F35-hGCC-PADRE vaccine administration, delivered intramuscularly (IM) at three dose levels (10^{11}, 10^{12}, and $5x10^{12}$ vp) 4 weeks apart in subjects with high-risk colorectal, pancreatic, gastric, or esophageal adenocarcinomas with no evidence of disease after surgery and standard therapy.

2) Evaluate the cellular (T-cell) responses to Ad5.F35-hGCC-PADRE at three different dose levels (10^{11}, 10^{12}, and $5x10^{12}$ vp) administered intramuscularly (IM) as three sequential doses 4 weeks apart in subjects with high-risk colorectal, pancreatic, gastric, or esophageal adenocarcinomas with no evidence of disease after surgery and standard therapy.