Phase III Study of PANVAC™-VF for Stage IV Pancreatic Cancer

THERION BIOLOGICS

Title:

A Phase III Randomized, Controlled Study to Evaluate the Safety and Efficacy of PANVAC-VF in Combination with GM-CSF Versus Best Supportive Care or Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas Who Have Failed a Gemcitibine-Containing Chemotherapy Regimen

Primary Endpoint:

Overall survival (OS), a logrank test will be performed to compare OS in the vaccine arm in combination with GM-CSF versus best supportive care or palliative chemotherapy (investigator's choice) in patients with metastatic adenocarcinoma of the pancreas.

Secondary Endpoints:

1. Quality of life parameters;
2. Change in serum CEA and CA19-9 levels;
3. Response rate;
4. Safety.

PANVAC™-VF:

PANVAC-VF is an investigational cancer vaccine. The vaccine was developed based on the theory that a T-cell mediated immune response can target and destroy cancer cells expressing specific tumor-associated antigens (TAA). This clinical study will test the clinical safety and efficacy of PANVAC-VF in patients with pancreatic cancer.

The vaccine comprises two separate vaccine vectors, each of which contains genes encoding CEA and MUC-1 plus three costimulatory molecules (LFA-3, ICAM-1, and B7.1).

Protocol Outline:

Approximately 250 patients will be randomized 1:1 (PANVAC-VF: best supportive care or palliative chemotherapy). PANVAC-V (prime) will be administered on Day 0, PANVAC-F (boost) is administered week 2, 4, 6, 8, 12, 16, and every 4 weeks thereafter.

Inclusion Criteria:

- Patients > 18 years of age who have been vaccinated against smallpox;
- Histologically confirmed diagnosis of adenocarcinoma of the pancreas;
- Patient has metastatic (stage IV) disease;
- ECOG performance status of 0-1;
- Failed a gemcitibine-containing chemotherapeutic regimen within 3 months of study entry.

Exclusion Criteria:

- Prior or concurrent immunotherapy for cancer;
- Radiation therapy within 28 days prior to registration;
- Systemic corticosteroid therapy (except inhaled or topical steroids) within 28 days of registration;
- Significant cardiovascular abnormalities or diseases;
- Known positive for HIV, hepatitis B and/or C;
- Evidence of immunodeficiency or immune suppression.

Please note, there are additional eligibility criteria