VERISTAT

Successful Full-Service, Randomized Pancreatic Cancer Phase II Trial

A Unanimous Decision After Safety Review Committee Data Review Meeting to Close Phase II and Advance to Phase III

Background

A clinical-stage biopharmaceutical company approached Veristat in a multi-center, randomized Phase II study of a modified synthetic peptide in patients with exocrine pancreatic cancer. The study aimed to establish the efficacy and safety of various combinations of the therapy in patients with stage IV exocrine pancreatic cancer. The sponsor engaged our team for biostatistics and programming, data management, monitoring and site management, medical safety, quality assurance, and medical writing, eventually leading to continued collaboration in the Phase III study.

Study Demographics

Indication

Metastatic exocrine pancreatic cancer

Primary Services Provided

- Biostatistics & Programming
- Data Management
- Monitoring & Site Management
- Medical Safety
- Quality Assurance
- Medical Writing

Sites

20 sites located across US

(14 USOR, 6 non-USOR)

CHALLENGES AND SOLUTIONS

The novel biologic was administered to patients who were randomized 1:1:1:1 in four treatment groups. Patients were to receive no more than four cycles of combination therapy, followed by six cycles of monotherapy in the absence of disease progression after the fourth cycle. Fleming's two-stage design was used for the primary endpoint.

Challenges	Solutions
Slow recruitment – some sites had a very long start-up timeline, 4 non-enrollers, requirement for white blood cells (WBC) <10,000 at screening	Newsletters; enrollment booster pep rally; follow-up by clinical research associates (CRAs), site management associates (SMAs) and medical monitor (MM); repeat screening lab test, one patient rescreened
Data cleaning post-MSU (mid-study updates)	Electronic data capture (EDC) bugs fixed in MSU; re-entry and repeated source data verification (SDV) of lab results
High volume of site documents across multiple sites	Additional resources were approved to get filing back on track. The Site Management and Documentation (SM&D) team have increased the number of post-approval Trial Master File (TMF) QCs per month to ensure that the TMF is up to date prior to site close-out visits (COVs).
Multiple site location and staff changes without SMA being notified	SMA team reviewed sites' folders on a monthly basis to collect and file new staff documents
Several sites' internal processes significantly differ from Veristat regarding document collection, filing, monitoring, etc.	Multiple Notes to Follow (NTF) and Controlled Document Deviation forms (CDDFs) were implemented to document these inconsistencies (lack of site qualification visits [SQVs], local lab documents, CV collection, 1572 updates, etc.)

ABOUT VERISTAT

Bold Thinking that Delivers Results for Your Novel Therapy

Our bold thinkers deliver integrated, flexible solutions to advance the most complex, rare, and advanced therapy treatments to market. Learn how Veristat helps navigate the complex challenges of accelerating therapies through clinical development to regulatory approval and commercialization.

IMPACT

The sponsor decided not to proceed to stage 2 and to close the Phase II study upon the recommendation of the Safety Review Committee, since the primary endpoint was met and there were no safety concerns.

After the commencement of a successful Phase II study, Veristat continues full-service support in the Phase III study with eyes toward an NDA submission.

"We chose to work with Veristat because they came highly recommended with positive feedback. I was more than impressed by the team that supported our Phase II trial. We are happy to continue working with that team on the Phase III trial."

—CEO, Clinical Stage Biopharma Company

Contact Veristat Today

To learn more about Veristat or how our expertise can assist you, reach out to us today.

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