clinical studies

pancreas

Comparing the Effect of Local Therapy (MDT) in Combination with Systemic Therapy to Systemic Therapy Alone on Outcomes in Patients with Oligometastatic Pancreatic Cancer (EXPAND)

MDT Metastasis Directed Therapies

PRINCIPAL INVESTIGATOR

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SITE ENROLLING

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ClinicalTrials.gov ID:
NCT06593431

artidis

Timely Diagnosis | Optimized Therapy

Phase 3 | Type **Interventional** | Allocation **Randomized** | Interventional Model **Single Group Assignment** | Masking **None (Open Label)** | Primary Purpose **Treatment**

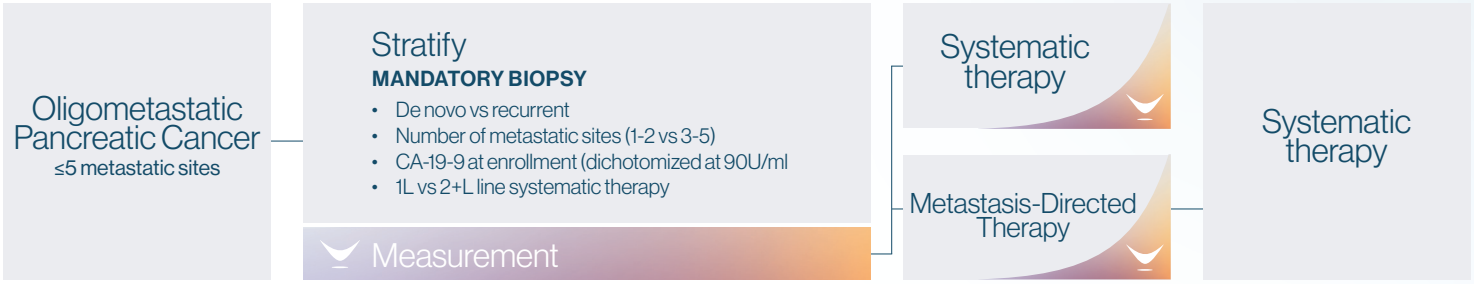
Brief Summary

The EXPAND trial (EXtending outcomes for PAncreas cancer patients with Nominal oligometastatic Disease) is a randomized phase III trial assessing the efficacy of metastasis-directed therapy (MDT) to improve PFS and OS for patients with oligometastatic pancreatic ductal adenocarcinoma (PDAC).

Clinical Relevance

Current biomarkers for pancreatic cancer are often suboptimal due to limitations in sensitivity, specificity, and variability among patients, which can hinder early detection and accurate disease monitoring. In response, ARTIDIS—a nanomechanical signature-based approach—ill be included as a clinical endpoint to evaluate treatment optimization by stratifying patients based on their ARTIDIS Nanomechanical Signature, offering a potentially cost-effective, high-impact method for improving patient outcomes.

Study Schema



Study Population

Histologically or cytologically confirmed stage IV pancreatic ductal adenocarcinoma patients also with confirmation of distant metastatic disease that are candidates for MDT (including radiation therapy, surgical resection, ablation, and embolization) to all sites of disease including oligometastatic sites and if present intact primary / regional nodal disease.

No. of Patients
128

Age
≥18y

Study Duration & Read-Outs

Enrollment Start
Q4 2024

Enrollment
2.5 years

Follow Up
2 years

Key Inclusion

- Histologically or cytologically confirmed stage IV pancreatic ductal adenocarcinoma.
- Histologic/cytologic confirmation of pancreatic ductal adenocarcinoma may come from the primary tumor (i.e., via FNA at initial diagnosis). Histological/pathologic confirmation of distant metastatic disease if clinical and radiographic consensus is that the patient has distant metastatic disease.
- Candidate for MDT to all sites of disease including oligometastatic sites and if present intact primary/regional nodal disease.

Key Exclusion

- Metastatic effusion (e.g. pleural effusion or ascites). Note that patients with an effusion that is too small to sample will be eligible for the trial.
- Leptomeningeal disease or/and peritoneal carcinomatosis.
- Diffuse bone marrow involvement as defined by disease involvement of a BM biopsy from a site that does not have radiologic evidence of a bone metastasis.
- More than 4 prior lines of systemic therapy to treat metastatic disease.
- Diagnosis of active scleroderma, lupus, or other rheumatologic disease which in the opinion of the treating radiation oncologist precludes safe delivery of radiotherapy. Such patients may be eligible if dispositioned to non-radiotherapy MDT.

SPONSOR & PARTNERS

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Artidis AG

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For any questions about this study or to express your interes in participating, please reach out to our research team at:

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