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Pancreatic Ductal AdenocarcinomaAdenocarcinoma

A study comparing the effects of an individualized drug product (autogene cevumeran) given in combination with an immunotherapy (atezolizumab) and chemotherapy (mFOLFIRINOX) compared to chemotherapy alone as post-surgery therapy in people with a type of cancer of the pancreas called pancreatic ductal adenocarcinoma (PDAC) after it has been surgically removed

A Study of the Efficacy and Safety of Adjuvant Autogene Cevumeran Plus Atezolizumab and mFOLFIRINOX Versus mFOLFIRINOX Alone in Participants With Resected PDAC

Trial Status	Trial Runs In	Trial Identifier
Recruiting	10 Countries	NCT05968326 2022-502404-73-00 GO44479

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Open-Label, Multicenter, Randomized Study of the Efficacy and Safety of Adjuvant Autogene Cevumeran Plus Atezolizumab and mFOLFIRINOX Versus mFOLFIRINOX Alone in Patients With Resected Pancreatic Ductal Adenocarcinoma

Trial Summary:

The purpose of this study is to evaluate the efficacy and safety of adjuvant autogene cevumeran plus atezolizumab and modified leucovorin, 5-fluorouracil (5-FU), irinotecan, and oxaliplatin (mFOLFIRINOX) versus mFOLFIRINOX alone in participants with resected pancreatic ductal adenocarcinoma (PDAC) who have not received prior systemic anti-cancer treatment for PDAC and have no evidence of disease after surgery.

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT05968326 2022-502404-73-00 GO44479
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#18 Years	No

1. Why is the IMCODE003 clinical trial needed?

This clinical trial addresses a need to identify improved post-surgery therapies for people with a type of cancer of the pancreas called pancreatic ductal adenocarcinoma (PDAC). The majority of patients who have their PDAC removed (resected) and receive current standard-of-care chemotherapy either experience their disease coming back (recurrence) or die from their disease despite this aggressive therapy. This clinical trial aims to compare the effects of an individualized drug product called autogene cevumeran, given in combination with atezolizumab and mFOLFIRINOX, compared to mFOLFIRINOX alone as post-surgery therapy in people with resected PDAC. Autogene cevumeran is an individualized drug product that will be made specifically for each participant from their tumor tissue routinely collected at surgery and blood samples. It is designed to activate and train the immune system to find and kill cancer cells. Atezolizumab is a drug designed to help the immune system kill cancer cells. Autogene cevumeran and atezolizumab are considered experimental treatments for participants who recently underwent surgical removal of newly diagnosed PDAC.

2. How does the IMCODE003 clinical trial work?

This clinical trial is recruiting people with PDAC. People can take part if they have PDAC that has been surgically removed and it has been determined that autogene cevumeran can be manufactured from their tumor tissue and blood samples that were collected and tested during screening. People who take part in this clinical trial will be given either the experimental treatment, autogene cevumeran in combination with atezolizumab and mFOLFIRINOX, or standard-of-care post-surgery therapy, mFOLFIRINOX. Clinic visits will include treatment and checks to see how the participant responds to the treatment and any side effects that may occur. The total time of participation in the clinical trial is expected to range from 1 day for those who choose to leave the trial to more than 6 years for those who continue to be followed. Participants can stop trial treatment and leave the clinical trial at any time.

Additionally, participants may have the option to join a substudy that will evaluate autogene cevumeran plus atezolizumab and mFOLFIRINOX using an alternative schedule to the main clinical trial.

3. What are the main endpoints of the IMCODE003 clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked) is disease-free survival (DFS) after study enrollment, defined as the time from enrollment to one of the following: first recurrence of PDAC or first occurrence of a new cancer, as determined by the clinical trial doctor, or death from any cause (whichever occurs first).

The other clinical trial endpoints include:

- DFS rates at 12, 24, and 36 months after enrollment, defined as the probability that the participant will not experience recurrence of PDAC or occurrence of new cancer, as determined by the clinical trial doctor, or death from any cause
- Overall survival (OS) after enrollment, defined as the time from enrollment to death from any cause
- OS rates at 3 and 5 years, defined as the probability that the participant will be alive at 3 and 5 years after enrollment
- Incidence and severity of side effects
- Change in targeted vital signs
- Change in targeted clinical laboratory test results

For the substudy, the main clinical trial endpoints include:

- Incidence and severity of side effects
- Change in targeted vital signs
- Change in targeted clinical laboratory test results

4. Who can take part in this clinical trial?

People can take part in this trial if they have PDAC that has been resected, have not received prior anti-cancer treatment for PDAC, have not had their spleen removed, and have no evidence of disease after surgery.

5. What treatment will participants be given in this clinical trial?

Everyone who joins the main clinical trial will be placed into one of two groups randomly (like flipping a coin) and given either:

- autogene cevumeran plus atezolizumab and mFOLFIRINOX
- mFOLFIRINOX alone

All study drugs are given as IV (into the vein) infusions. Participants will have a 50% chance of being placed in either group. This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

For the substudy, everyone who joins will receive:

- autogene cevumeran plus atezolizumab and mFOLFIRINOX using an alternative schedule/timing

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial
Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial. Safety assessments will be performed regularly.

Autogene cevumeran, atezolizumab, and mFOLFIRINOX chemotherapy
Participants will be told about the known side effects of autogene cevumeran, atezolizumab, and mFOLFIRINOX, as well as possible side effects based on human and laboratory studies or knowledge of similar drugs. Autogene cevumeran, atezolizumab, and mFOLFIRINOX will be given as an IV infusion.

Potential benefits associated with the clinical trial The health of participants may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

Inclusion Criteria:

- Histologically confirmed diagnosis of PDAC
- Pancreatic cancer tumor, lymph node, metastasis (TNM) pathological staging values of T1-T3, N0-N2, and M0 per the American Joint Committee on Cancer (AJCC) Cancer Staging Manual
- Macroscopically complete (R0 or R1) resection of PDAC
- Unequivocal absence of disease after surgery as assessed by the investigator within 28 days prior to randomization
- CA19-9 level measured within 14 days prior to initiation of study treatment
- Interval of between 6 and 12 weeks since resection of PDAC
- Full recovery from surgery and ability to receive atezolizumab, autogene cevumeran, and mFOLFIRINOX in the investigator's judgment
- Adequate hematologic and end-organ function
- Female participants of childbearing potential must be willing to avoid pregnancy during the treatment period and for 28 days after the final dose of autogene cevumeran, for 9 months after the last dose of chemotherapy, and for 5 months after the final dose of atezolizumab. They must refrain from donating eggs for 9 months after the last dose of chemotherapy.
- Male participants with a female partner of childbearing potential or pregnant female partner must remain abstinent or use specified contraceptive methods during the treatment period and for 28 days after the final dose of autogene cevumeran and for 6 months after the last dose of chemotherapy. Men must refrain from donating sperm during this same period.

Exclusion Criteria:

- Prior adjuvant, neoadjuvant, or induction treatment for pancreatic cancer
- Plan for further adjuvant anti-cancer therapy for PDAC (e.g., radiotherapy and/or chemotherapy), not mandated per protocol, to be initiated after completion of mFOLFIRINOX treatment
- Absence of spleen; distal pancreatectomy with splenectomy is exclusionary
- Preexisting Grade >/=2 neuropathy
- Known complete dihydropyrimidine dehydrogenase (DPD) deficiency including homozygous or compound heterozygous mutations of DPYD genetic locus associated with DPD deficiency
- Disorders of the colon or rectum, or postoperative complication leading to Grade >/=2 diarrhea
- Pregnancy or breastfeeding
- Active or history of autoimmune disease or immune deficiency
- Treatment with brivudine, sorivudine, or their chemically-related analogues, which are inhibitors of DPD, within 4 weeks prior to initiation of study treatment
- Current or planned treatment with strong inhibitors or inducers of cytochrome P450 3A4 (CYP3A4) and/or uridine diphosphate glucoronosyltransferase 1A1 (UGT1A1).