ForPatients
by Roche

Breast Cancer Solid Tumors Cancer

A study to evaluate the safety, tolerability, processing by the body, and antitumor activity of inavolisib and paclitaxel

A Phase Ib, open-label, dose-escalation and dose-expansion study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of inavolisib in combination with paclitaxel in patients with locally advanced or metastatic solid tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	7 Countries	2023-506745-33-00, ISRCTN45319897 CO42800

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study will evaluate the safety (side effects), how the body processes the treatment (pharmacokinetics), what the treatment does to the body (pharmacodynamic effects), and preliminary anti-cancer activity of the drug inavolisib given in combination with the drug paclitaxel in patients with locally advanced or metastatic solid tumors, and of inavolisib given in combination with paclitaxel, in patients with locally advanced or metastatic PIK3CA-mutated (altered gene), HER2-positive breast cancer. Locally advanced cancer is cancer that has spread only to nearby tissues or lymph nodes, while metastatic cancer is cancer that has spread to other parts of the body.

Genentech, Inc (USA) Sponsor	**Phase 1** Phase

2023-506745-33-00, ISRCTN45319897 CO42800
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male and Female	18 and up	no

1. Why is the CO42800 clinical trial needed?

Solid tumour cancers are cancers that grow in any of the body’s organs or tissues. Standard treatment includes surgery, chemotherapy and radiotherapy. Medicines that help the body’s immune system fight cancer are also used. Yet, treatments can cause side

effects, do not work for everyone, or stop working as time passes. So, new treatments are needed, especially for cancers that have grown and cannot be removed with surgery or that have spread to other parts of the body.

Inavolisib is an experimental drug. This means health authorities have not approved it for treating cancer. Inavolisib blocks a signal that cancer cells use to grow and multiply. This signal is called the PI3K pathway. In some cancers, the *PIK3CA* gene has changed or mutated. This *PIK3CA* mutation affects the PI3K pathway. As a result, cells grow and multiply more than normal. Researchers think that adding inavolisib to paclitaxel chemotherapy may improve treatment of certain cancers.

This clinical trial aims to test the safety of inavolisib and how well it works together with paclitaxel at different doses. Researchers will also look at how the body reacts to inavolisib plus paclitaxel. The trial will be in people with cancers that have grown or spread.

2. How does the CO42800 clinical trial work?

This clinical trial is recruiting people with solid tumour cancers that have grown or spread. People can take part if previous treatment has not worked, or it caused unacceptable side effects. People who take part in this clinical trial (participants) will be given the clinical trial treatment inavolisib plus paclitaxel for as long as it can help them. Treatment will be given in ‘cycles’ – a cycle is the treatment and recovery time, and each cycle will last 28 days. The clinical trial doctor will see participants 6 times in Cycle 1 then 4 times in all later cycles. Participants who stop having paclitaxel (for example, because it caused unacceptable side effects) may continue taking inavolisib and will be seen once a month. These hospital visits will include checks to see how participants respond to the treatment and any side effects they may have. Total time of participation in the clinical trial could range from 6 months to around 2 years, or longer if they benefit from the clinical trial treatment. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the CO42800 clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see how safe inavolisib together with paclitaxel is) are the maximum doses that can be given without unacceptable side effects, and the number and seriousness of any side effects.

The other clinical trial endpoints include:

- Number of participants whose cancers get smaller and the amount of time this lasts if the cancer then grows or spreads
- Number of participants whose cancers get smaller or stay the same size for at least 6 months after treatment
- The amount of time between the start of the trial treatment and participants’ cancer possibly growing or spreading

- How the body breaks down and reacts to inavolisib when given with paclitaxel

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old. Participants that can become pregnant must agree to not have heterosexual sex or to use a reliable birth control method (and their male partners must use a condom with spermicide unless sterilization is confirmed) during the trial, for 6 months after the final dose of paclitaxel and 2 months after the final dose of inavolisib. During the trial and for up to 4 months after the final dose of paclitaxel and/or inavolisib, male participants must not donate sperm, must not have sex or use a condom plus another reliable birth control method if their partner is able to become pregnant, and those with pregnant partners must not have sex or use a condom. Participants must also agree to have a blood sample taken. People may not be able to take part in this trial if they have been given certain treatments or could not tolerate paclitaxel. People with diabetes and certain other diseases, infections or cancer that has spread to the brain and spinal cord may also not be able to take part.

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

Everyone who joins this clinical trial will be given treatment in 28-day cycles, as follows:

- Inavolisib, given as a tablet(s) (to be swallowed) daily
- Paclitaxel, given as an infusion (into the vein) on Days 1, 8, and 15 of each cycle and also optionally on Day 22 for each cycle

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.

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

The safety or effectiveness of the experimental treatment or use 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 drugs

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.

Participants will be told about the known side effects of inavolisib and paclitaxel and possible side effects based on human and laboratory studies or knowledge of similar drugs. Inavolisib will be given as a tablet (to be swallowed) and paclitaxel as an infusion into the vein (intravenous infusion). Participants will be told about any known side effects of swallowing tablets and intravenous infusions.

Potential benefits associated with the clinical trial

Participants' health 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.