

A study of E7386 in people with certain advanced cancers

Full Study Title:	An Open-Label, Multicenter, Phase 1 Study of E7386 in Subjects With Selected Advanced Neoplasms		
EU Clinical Study Number:	2016-004881-25	US Clinical Study Number:	NCT03264664
Study Sponsor:	Eisai, Inc., Nutley, NJ, USA	Telephone number:	+1 201-692-1100

Why is this research needed?

Researchers are looking for a different way to treat people who have certain advanced cancers. Cancer is a disease in which abnormal cells grow out of control and can spread to other parts of the body. This study includes people whose cancer had grown or spread, could not be removed with surgery, had come back or got worse after their last treatment, and who had no other standard treatment options available.

E7386 may help people with certain advanced cancers by blocking the proteins responsible for the formation and growth of the cancer cells.

In this 2-part study, researchers want to learn about the safety profile of E7386 and how well it may work in participants with certain advanced cancers.

What treatment is being studied?

E7386 is designed to block the interaction of a specific group of proteins that can help cancer cells grow and become harder to treat.



Participants will take E7386 as capsules or tablets twice daily by mouth in 28-day periods called treatment cycles.



Participants may continue taking E7386 until their cancer gets worse, they have intolerable medical problems, they choose to stop, or the study ends.



All people involved in the study will know that the participants will take E7386. This is called an open-label study.

What are the goals of this study?

The primary objectives of this study are to investigate the safety profile of E7386 and to find out the appropriate dose of E7386, which will be used in Part 2 of the study.

The secondary objectives are to investigate how well E7386 may work in certain cancers and how it moves through the body and is cleared from the body.

What are the measurements in this study?

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Main measurement: To investigate the primary objectives, researchers will collect information on any medical problems that participants may have during the study, including medical problems that will prevent participants from taking a higher dose of E7386, which are called dose-limiting toxicities.

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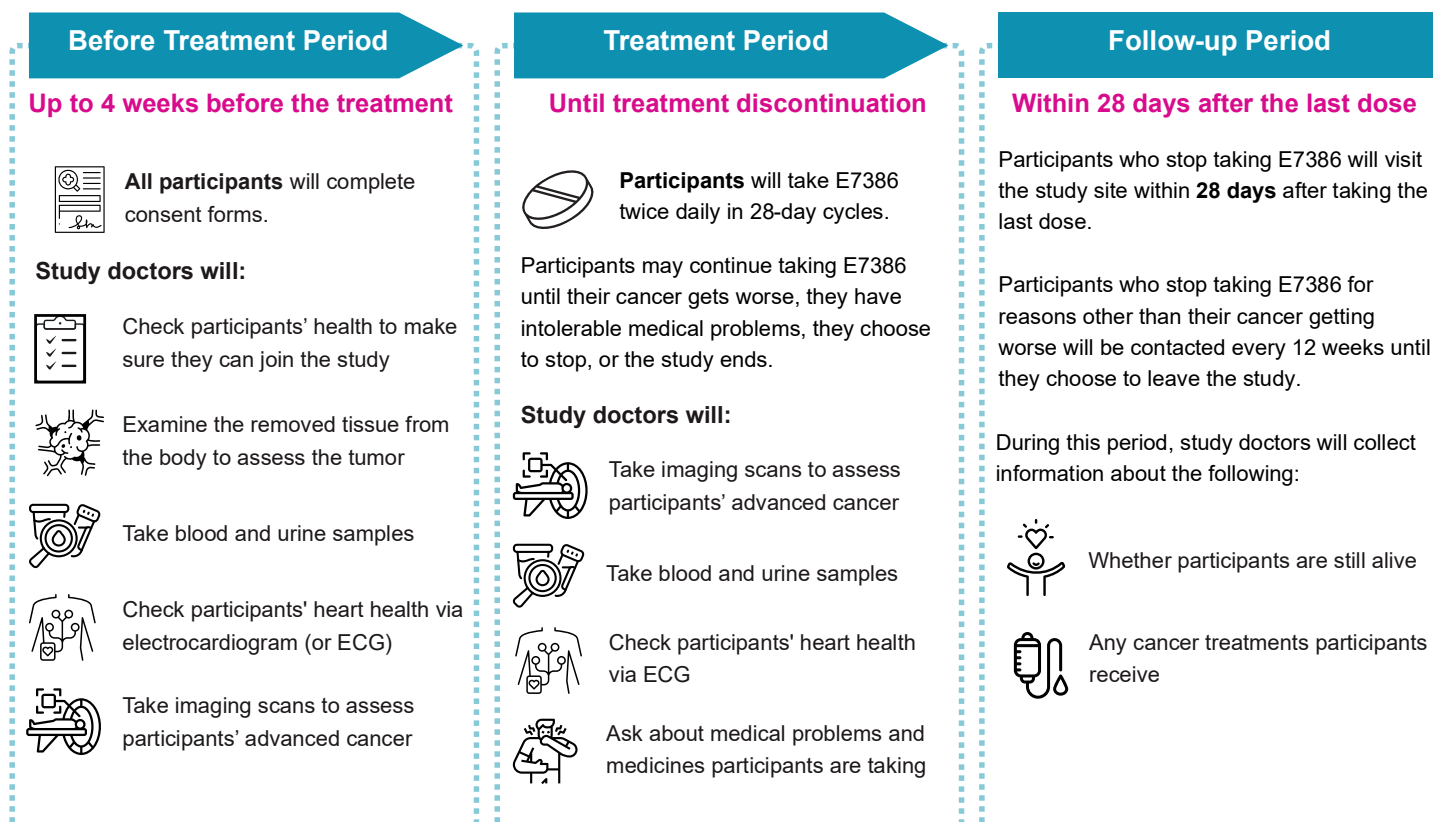
Secondary measurements: To investigate the secondary objectives, researchers will check the objective response rate (ORR) and progression-free survival (PFS) and will measure the amount of E7386 in the blood.

- **ORR** is the proportion of participants whose cancer cells have a partial (decrease in size) or complete (gone away) response to treatment.
- **PFS** is the length of time that participants live without their cancer getting worse after starting treatment.

The researchers will also collect other information about E7386, but the measurements described above are the most important for this study.

What will happen during the study?

The chart below shows what will happen in both parts of the study.



Who can and cannot take part in this study?



People can take part in this study if they:

- Are at least 18 years old
- Have certain advanced cancers that had spread to another part of the body, could not be removed with surgery, had come back or got worse after their last treatment, and had no other standard treatment options available
- Expected to live for at least 3 months



People cannot take part in this study if they:

- Have any other type of cancer that are not included in the study
- Received other cancer treatment within 4 weeks before starting study treatment

These are just some of the main study entry guidelines. Study doctors will check all of the requirements to see if a person can join this study. Participation in this study is voluntary. Participants can leave the study at any time.

What are the potential benefits and risks of taking part in this study?

Potential benefits (advantages): E7386 may help treat certain advanced cancers. The information collected in this study may help doctors learn more about E7386 that could help people with certain advanced cancers.

Potential risks (disadvantages): E7386 may not help treat certain advanced cancers, or participants may have side effects from E7386. There may be additional risks that are unknown and unexpected.