If you or a loved one were recently diagnosed with gastric (stomach) cancer or cancer that is between the stomach and esophagus or food pipe, you may want to learn more about the LUCERNA Study.

The clinical study is testing the study drug called zolbetuximab (ZOL-BEH-TOOKS-I-MAB). This drug is given with an approved immunotherapy treatment called pembrolizumab, in combination with standard-of-care chemotherapy for adults with untreated, locally advanced, or metastatic (spread to other parts of the body) gastric cancer. Immunotherapy is a form of treatment that helps your own immune system fight cancer. Study participants must have a tumor protein (a large complex molecule) called Claudin 18.2. The tumor must also have a protein called PD-L1 and it should not have a protein called HER2. If you are unsure if your cancer meets these criteria, the study staff will be able to help you find out.

How Does Zolbetuximab Work?

Zolbetuximab is a type of cancer drug that specifically targets a protein called Claudin 18.2. This is why it is important to know that the tumor has this protein, Claudin 18.2, before you can join this study. If the tumor has Claudin 18.2, zolbetuximab will attach to it, and this will signal your immune system to recognize and destroy the cancer cells.

Please talk to a study team member to learn more about the LUCERNA Study.

If you'd like more information or have any questions about the LUCERNA Study, please contact:

https://www.clinicaltrials.astellas.com/study/8951-CL-0305

8951-CL-0305-Brochure_US Eng_QR Code_v1.0_21JAN2025

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HAVE YOU OR A LOVED ONE BEEN DIAGNOSED WITH GASTRIC (STOMACH) CANCER?

Learn more about the **LUCERNA Study**, a clinical research study accepting new participants

LUCERNA

About the LUCERNA Study

The study is assessing the safety and effectiveness of zolbetuximab, in combination with pembrolizumab and 2 different chemotherapy treatments (CAPOX or mFOLFOX6), compared with placebo plus pembrolizumab and the same chemotherapy alternatives.

A placebo looks like the drug being tested but has no active ingredients.

Study Details:

Screening period: The study starts with a screening period. During this time, you will sign a consent form, answer questions about your health, have blood tests, and possibly undergo imaging scans. These steps will determine if the study is right for you. After screening, eligible participants will begin treatment, and will be assigned randomly (as if by flipping a coin) to 1 of 2 treatment groups:

- **Group A:** Zolbetuximab in combination with pembrolizumab and chemotherapy (CAPOX or mFOLFOX6).
- **Group B:** Placebo in combination with pembrolizumab and chemotherapy (CAPOX or mFOLFOX6).

You have a 50% chance of being assigned to either group. Whether assigned to take zolbetuximab or placebo, you will receive pembrolizumab with chemotherapy (mFOLFOX6 or CAPOX). Treatments are given intravenously (into a vein) or as an oral tablet (one of the CAPOX chemotherapy drugs). The treatment phase will last multiple cycles (each lasting approximately 42 days), depending on your response to treatment.

Follow-up: After treatment, you will have follow-up visits to check your health 30 days and 90 days after your last treatment. Long-term follow-ups will occur every 12 weeks to monitor your progress, which may include imaging scans.

Who Can Participate?

To join the LUCERNA Study, you must:

- Be diagnosed with locally advanced unresectable or metastatic gastric cancer
- Be at least 18 years of age
- Have not had treatment for metastatic or unresectable disease before, except for 1 dose of mFOLFOX6 or CAPOX, with or without pembrolizumab
- Have a tumor with specific proteins called Claudin 18.2 and PD-L1
- Have a tumor without a specific protein called HER2

If you are unsure if your cancer meets these requirements, the study staff can help you decide if you can join. There are also other requirements for taking part.

Why Participate?

While you may not benefit directly from the LUCERNA Study, your participation can help researchers learn more about gastric cancer and potentially help others in the future. If you choose to participate, you will receive:

- Study medication or placebo together with standard cancer treatment
- Close medical care and follow-up throughout the study by cancer specialists
- Possible reimbursement for study-related expenses, including travel

About Clinical Studies

A clinical study (also called a clinical trial) is carefully supervised research that looks for ways to treat disease before an investigational product can be prescribed by physicians to patients.

- The results of clinical studies help determine if new treatments are safe and effective.
- Clinical studies are the only way to bring about new medical treatments to improve patient care.
- There are risks and benefits to participating in clinical studies, but the study team carefully watches participants, keeping the well-being of each participant as the primary focus.

Participation in the LUCERNA Study is completely up to you. Deciding not to take part will not affect your medical care now or in the future. If you take part, you may leave the study at any time and for any reason.

Even if you don't directly benefit from a clinical study, your participation contributes to valuable scientific knowledge about a disease or condition that may help others in the future. People who take part in clinical studies are vital to the process of improving medical care.

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