A clinical study of pembrolizumab for treating liver cancer after it has been removed by surgery or ablation (MK-3475-937)

Protocol Title: A Phase 3 Double-blinded, Two-arm Study to Evaluate the Safety and Efficacy of Pembrolizumab (MK-3475) versus Placebo as Adjuvant Therapy in Participants with Hepatocellular Carcinoma and Complete Radiological Response after Surgical Resection or Local Ablation (KEYNOTE-937)

Why is this study needed?

Researchers are looking for new ways to treat people with **liver cancer.** People with liver cancer often have surgery to remove cancer or **ablation. Ablation** is treatment that destroys liver tumors without removing them using high-energy radio waves or microwaves. Some people have a higher chance (risk) of cancer coming back after surgery or ablation.

Researchers want to know if treating people with pembrolizumab as **adjuvant therapy** after surgery or ablation can prevent cancer from coming back. **Adjuvant therapy** is treatment given after the first treatment to improve the chance the cancer will not return. **Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer.

The goal of this study is to learn if people who receive pembrolizumab live longer and are cancer free longer than those who receive placebo. A **placebo** looks like the study medicine but has no study medicine in it. A placebo is used when there are no current approved medicines to compare the study medicine to. Using a placebo helps researchers better understand if the study medicine works.

Who will take part in this study?

About 950 people with liver cancer will be in the study. They will be at least 18 years old and:

- Have had surgery or ablation and have no signs of cancer
- Have a higher risk of cancer coming back
- Have not had another cancer besides liver cancer

What treatments are being given during the study?

People will have an equal chance of receiving either:

- **Pembrolizumab**, the study medicine
- **Placebo**

Pembrolizumab or placebo will be given through a needle into a vein as an infusion every 3 weeks for about 1 year.

How is this study designed?

A person may be in this study for up to 8 years.

Neither the people in the study nor the researchers will know what treatment a person receives (called a **double-blind study**).

People may have urine, blood, tumor, and imaging tests, have physical examinations and answer questions during the study.

What are the goals of this study and how will they be measured?

Main goal	How they will be measured
To learn if people who receive pembrolizumab have longer **recurrence-free survival (RFS)** compared to people who receive placebo	**RFS** is the length of time from when the person starts the study until either the cancer comes back, the cancer spreads, or death from any cause.
To learn if people who receive pembrolizumab live longer **(overall survival-OS)** compared to people who receive placebo	**OS** is the length of time that people live from the start of treatment until death from any cause.

Other goals	How they will be measured
To learn if pembrolizumab is safe and how well people tolerate it	The number of people who: • Had an **adverse event (AE)** – An AE is a health problem that happens or worsens during a study. • Stopped treatment due to an AE
To learn about how people who receive pembrolizumab or placebo score on **health-related quality of life (HRQoL)** questionnaires	People will answer questions to measure their HRQoL including questions about their overall health and the ability to carry out daily tasks. Researchers will measure the change in the scores during the study.

What are the possible benefits and risks?

People in this study may or may not have the cancer come back. This study has an external group of experts that will oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe or does not show benefit, the study can be stopped.

More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.