Phase 2 study of adjuvant V940 and pembrolizumab in renal cell carcinoma (V940-004)

Protocol Title: A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants With Renal Cell Carcinoma

Why is this study needed?

Researchers continue to look for improved ways to treat **renal cell carcinoma (RCC)**, the most common type of kidney cancer. People with RCC often have surgery to remove the cancer. After surgery, people who have a high chance (risk) of cancer returning receive more treatment **(adjuvant treatment)**. **Pembrolizumab** is a standard treatment given after surgery to prevent RCC from returning. Pembrolizumab is an immunotherapy, which is a treatment that helps the immune system fight cancer.

Researchers want to learn if **V940 (study treatment)** in combination with pembrolizumab can help prevent RCC from returning after surgery. V940 is designed to help a person's immune system attack their specific cancer.

The goal of this study is to learn if people who receive V940 and pembrolizumab are alive and cancer free for longer than those who receive placebo and pembrolizumab. A **placebo** looks like the study treatment but has no active treatment in it. Using a placebo helps researchers better understand if the study treatment works.

Who will take part in this study?

About 272 people with RCC will be in the study. They will be 18 years old and older and:

- Had surgery to remove RCC and have a high chance of cancer returning
- Not have had other treatment for RCC besides surgery

What treatments are being given during the study?

People will have an equal chance of receiving either:

- **V940** (study treatment) and **pembrolizumab**
- **Placebo** and **pembrolizumab**

V940 or placebo will be given as an injection (shot) into the muscle every 3 weeks for about 6 months.

Pembrolizumab will be given through a needle into a vein as an infusion every 6 weeks for about 1 year.

How is this study designed?

A person may be in this study for up to 8 years including follow-up time.

Neither the people in the study nor the researchers will know what treatment they are assigned to (called a **double-blind study**). During the study, people will give blood, urine, and tumor samples, have imaging tests and physical examinations, and answer questions about their health.

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

Main goal	How it will be measured
To learn if people who receive **V940** and pembrolizumab have longer **disease-free survival (DFS)** compared to people who receive placebo and pembrolizumab	**DFS** is the length of time that people are alive and cancer free
Other goals	**How they will be measured**
To learn about the **distant metastasis-free survival (DMFS)** of people who receive **V940** and pembrolizumab compared to people who receive placebo and pembrolizumab	**DMFS** is the length of time that people are alive until the cancer spreads from the kidney to other parts of the body
To learn about the **overall survival (OS)** of people who receive **V940** and pembrolizumab compared to people who receive placebo and pembrolizumab	**OS** is the length of time people are alive
To learn if **V940** 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

What are the possible benefits and risks?

People in this study may or may not have cancer return after getting the treatment in this study. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.