Protocol Plain Language Summary

A clinical study of pembrolizumab and lenvatinib in people with kidney cancer (MK-3475-B61)

Protocol Title: A Phase 2, Single-arm, Open-label Clinical Trial of Pembrolizumab Plus Lenvatinib in Participants with First-line Advanced/Metastatic Non-clear Cell Renal Cell Carcinoma (nccRCC) (KEYNOTE-B61)

Why is this study needed?

Researchers are looking for ways to treat people with advanced or metastatic **non-clear cell renal cell carcinoma (nccRCC)**, which is a type of kidney cancer. **Advanced** means cancer has spread outside the kidney. **Metastatic** means cancer has spread to other parts of the body.

Researchers want to learn if pembrolizumab and lenvatinib, 2 study medicines, can treat nccRCC. **Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer. **Lenvatinib** is a targeted therapy, which is a treatment that works to control how specific types of cancer cells grow and spread.

The goal of this study is to learn if people with nccRCC who receive pembrolizumab and lenvatinib have the cancer get smaller or go away.

Who will take part in this study?

About 152 people with advanced or metastatic nccRCC will be in the study. They will be ages 18 years and older and:

- Have not received treatment for advanced or metastatic nccRCC
- Do not have certain heart conditions

What treatments are being given during the study?

All people in the study will receive both of these study medicines:

- **Pembrolizumab** received every 6 weeks through a needle into a vein as an intravenous (IV) infusion
- **Lenvatinib** taken once a day by mouth as a capsule

People will receive pembrolizumab for up to 2 years, or until the cancer gets worse or they don't tolerate it. Some people may receive another year of pembrolizumab with researcher approval.

People will take lenvatinib until the cancer gets worse or they don't tolerate it.

How is this study designed?

Both the people in the study and the researcher will know which study medicines a person is getting (**open-label study**). People will give urine and blood samples, have tumor and imaging tests, have physical examinations, and answer questions during the study.

A person may be in this study for about 5 years.

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

Main goal	How it will be measured
To learn about the **objective response rate (ORR)** of people who receive pembrolizumab and lenvatinib	**ORR** is the number of people whose cancer **responds** to treatment (gets smaller or goes away) during the study
Other goals	**How they will be measured**
To learn about the **duration of response (DOR)** of people who receive pembrolizumab and lenvatinib	**DOR** is the length of time from when the cancer first responds to treatment until the cancer grows or spreads, or death from any cause
To learn about the **progression-free survival (PFS)** of people who receive pembrolizumab and lenvatinib	**PFS** is the length of time from the start of treatment until the cancer grows or spreads, or death from any cause
To learn about the **overall survival (OS)** of people who receive pembrolizumab and lenvatinib	**OS** is the length of time that people live from the start of treatment until death from any cause
To learn about the **clinical benefit ratio (CBR)** of people who receive pembrolizumab and lenvatinib	**CBR** is the number of people whose cancer gets smaller, goes away, or is stable (stays the same) for at least 6 months
To learn about the **disease control rate (DCR)** of people who receive pembrolizumab and lenvatinib	**DCR** is the number of people who have the cancer stop growing or get smaller, or show no signs of cancer
To learn if pembrolizumab and lenvatinib are **safe** and how well people tolerate them	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 may or may not benefit from the treatment received during the study. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.