A clinical study of MK-0482 in people with blood cancer (MK-0482-002)

Protocol title: A Phase 1b Study to Evaluate the Safety, Tolerability, and Pharmacokinetics/Pharmacodynamics of MK-0482 in Participants with Relapsed or Refractory Acute Myeloid Leukemia or Chronic Myelomonocytic Leukemia

Why is this study needed?

Researchers are looking for a new way to treat 2 types of blood cancer called **acute myeloid leukemia (AML**) and **chronic myelomonocytic leukemia (CMML)** that are relapsed or refractory. AML and CMML are blood cancers that start in cells that become white blood cells (cells that fight infection). **Relapsed** means the cancer has come back after it had responded to previous treatment. **Responded** means the number of cancer cells in the blood goes down or cancer goes away. **Refractory** means cancer did not respond or stopped responding to treatment.

The first treatment for AML and CMML is **chemotherapy**. Chemotherapy uses medicine to destroy cancer cells or stop them from growing. For some people, chemotherapy doesn't work, stops working to treat cancer, or cancer comes back after treatment.

Researchers want to learn if MK-0482 (the study medicine) can treat blood cancer that is relapsed or refractory. MK-0482 is an **immunotherapy**, which is a treatment that helps the immune system fight cancer.

The goal of this study is to learn about the safety of different doses (amounts) of MK-0482 and how well people tolerate it. Researchers also want to find the highest dose of MK-0482 that people can tolerate and may work to treat blood cancer.

Who will take part in this study?

Up to 35 people with relapsed or refractory AML or CMML will be in this study. They will be at least age 18 years and:

- Have been treated previously with chemotherapy
- Do not have cancer that has spread to the brain or spine

What treatments are being given during the study?

Everyone in the study will receive MK-0482 (the study medicine**).**

People will receive MK-0482 through a needle into a vein as an intravenous (IV) infusion once every 3 weeks for up to 2 years.

How is this study designed?

Each person may be in the study for about 2 years.

This study has 2 parts:

- **Part 1**: About 20 people with AML or CMML will receive 1 of 5 different dose levels of MK-0482. Researchers will start by giving a few people the lowest dose of MK-0482. They will check for safety concerns before giving other people the next higher dose.

Researchers will review the safety of the different dose levels of MK-0482 to decide which dose level to use in Part 2.

- **Part 2**: Up to 15 people with AML will receive the dose of MK-0482 that was chosen in Part 1.

Both the people in the study and the researcher will know which study treatment a person is getting (open-label study). During this study, people may give bone marrow, blood, and urine samples, and have physical examinations.

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

Main goals	How they will be measured
To learn the **highest dose of MK-0482** that people can tolerate during Part 1	The number of people in Part 1 who had a **dose limiting toxicity (DLT)** during the first 3 weeks of treatment – a DLT is a medical problem related to the study medicine that prevents giving a higher dose
To learn about the **safety** of MK-0482 and how well people **tolerate** it during Parts 1 and 2	Number of people in Parts 1 and 2 who: • Had an **adverse event (AE)** – an AE is a health problem that happens or worsens during the study • Stopped treatment due to an AE
Other goals	**How they will be measured**
To learn what happens to different doses of MK-0482 in a person's body over time	Researchers will measure the amount of MK-0482 in people's blood samples at different time points during the study
To learn how AML **responds** to MK-0482 in Part 2	Researchers will measure how AML responds during the study: • **Objective response rate (ORR):** The number of people whose cancer responds to treatment (the number of cancer cells in the blood goes down or cancer goes away) • **Complete remission (CR):** The number of people who do not show signs of AML after treatment • **Complete remission without improvement of all blood cell counts (CRi)**: The number of people who show little to no signs of AML after treatment but still have some low blood cell counts

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.