Protocol Plain Language Summary

A clinical study of zilovertamab vedotin in people with large B-Cell lymphoma (MK-2140-004)

Protocol title: A Phase 2 Open-label Clinical Study to Evaluate the Efficacy and Safety of Zilovertamab Vedotin (MK-2140) in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (waveLINE-004)

Why is this study needed?

Researchers are looking for better ways to treat people with diffuse large B-cell lymphoma (**DLBCL**). DLBCL is the most common type of non-Hodgkin's lymphoma (a blood cancer).

Doctors usually treat DLBCL with chemotherapy combined with immunotherapy (standard treatment). Chemotherapy uses medicines to destroy cancer cells, and immunotherapy uses medicines that work with the immune system to fight cancer.

In this clinical study, researchers want to learn about zilovertamab vedotin treatment for people with DLBCL. **Zilovertamab vedotin** is a type of targeted therapy. A targeted therapy is a treatment that works to control how specific cancer cells grow and spread.

The purpose of the study is to learn about the safety and how well people with DLBCL tolerate zilovertamab vedotin. Researchers also want to learn if zilovertamab vedotin works for people with DLBCL by measuring if more than 25 out of 100 people who take it have their cancer **respond to treatment** (cancer gets smaller or goes away).

Who will take part in this study?

About 140 people with DLBCL will be in this study. They will be at least 18 years and older, and:

- Have DLBCL which came back or did not respond to standard therapy
- Do not have a certain type of cancer called primary mediastinal B-cell lymphoma

What treatment is being given during the study?

During this study, people will receive zilovertamab vedotin once every 3 weeks through a needle into a vein as an intravenous (IV) infusion.

Each person will receive treatment until the cancer gets worse or they leave the study.

How is this study designed?

There are 2 groups in this study:

- Group 1 (about 100 people) will receive a **higher dose of zilovertamab vedotin**
- Group 2 (about 40 people) will receive a **lower dose of zilovertamab vedotin**

Both the people in the study and researchers will know which treatment dose the person receives because everyone will receive zilovertamab vedotin (an open-label study). During the study, people may have tumor, bone marrow, blood, urine, and imaging tests, have physical examinations, and answer sets of questions about their health.

People may be in this study for up to 4 years.

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

Main goal	How it will be measured
To learn the **objective response rate (ORR)** of people who receive zilovertamab vedotin	**ORR** is the number of people whose cancer responds to treatment during the study

Other goals	How they will be measured
To learn the **duration of response (DOR)** of people who receive zilovertamab vedotin	**DOR** is the length of time from when a person's cancer first responds to treatment until the cancer gets worse or death from any cause.
To learn about the **safety** and how well people **tolerate** zilovertamab vedotin	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 not benefit from treatment, such as having cancer stop growing or go away. More information about benefits and risks may be found in the Investigator's Brochure, Protocol, and Informed Consent documents.