A clinical study of MK-6194 for the treatment of vitiligo (MK-6194-007)

Protocol Title: A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MK-6194 in Adult Participants with Non-Segmental Vitiligo

Why is this study needed?

Researchers are looking for a new way to treat people with **non-segmental vitiligo (NSV)**. Vitiligo is a long-lasting disease that causes the loss of skin color in patches, which look like light-colored areas or areas with no color. These areas usually get bigger over time. NSV can appear anywhere on the body (non-segmental) and is more common than vitiligo that appears only on certain very defined areas (segments) of the body (segmental vitiligo).

Researchers use a scoring system called **vitiligo area scoring index (VASI)** to measure the area of skin with color loss due to vitiligo. Past studies have shown that **MK-6194** is a study medicine that researchers think could treat vitiligo.

The goal of this study is to learn about the safety of MK-6194 and how well people tolerate it. Researchers also want to learn if people who take MK-6194 have more of a decrease in the amount of vitiligo on their face after 24 weeks of treatment compared to people who take placebo. A **placebo** looks like the study medicine but has no study medicine in it. Using a placebo helps researchers better understand the effects of a study treatment.

Who will take part in this study?

About 165 people with NSV will be in this study. They will be between the ages of 18 and 75 years and:

- Have had NSV symptoms for at least 6 months
- Do not have certain, other skin diseases, including segmental vitiligo

What treatments are being given during the study?

People will receive one or both of these treatments as a shot given under their skin:

- **MK-6194**, the study medicine
- **Placebo**

How is this study designed?

A person may be in this study for up to about 1 year and 2 months. This study has 2 parts.

Part 1: People will have an equal chance to be assigned to 1 of 3 treatment groups and receive treatment for 24 weeks (about 6 months).

- **Group 1**: MK-6194
- **Group 2**: MK-6194 and placebo
- **Group 3**: Placebo

Part 2: People who complete Part 1 of the study may choose to continue study treatment for another 28 weeks (about 6.5 months). All people will receive MK-6194 during Part 2.

Neither the people in the study nor the researchers will know which treatment a person is taking (double-blind study). During the study, people will give blood and urine samples, have physical examinations and imaging tests including photographs, and answer questions about their vitiligo.

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

Main goals	How they will be measured
To learn if people who receive MK-6194 have more of a decrease in the amount of vitiligo on their face compared to people who receive placebo	The change in the amount of vitiligo on a person's face after 24 weeks of treatment, which will be measured using the **facial vitiligo area scoring index (F-VASI)**
To learn about the **safety** of MK-6194 and how well people **tolerate** treatment	During the study, the number of people who: • Had an **adverse event (AE)** – An AE is a health problem that happens or worsens • Stopped treatment due to an AE
Other goal	**How it will be measured**
To learn if people who receive MK-6194 have more of a decrease in the amount of vitiligo on their whole body compared to people who receive placebo	The change in the total amount of vitiligo on a person's body after 24 weeks of treatment, which will be measured using the **total body vitiligo area scoring index (T-VASI)**

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study. 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.