A clinical study of clesrovimab in infants and children (MK-1654-007)

Protocol Title: A Phase 3, Multicenter, Randomized, Partially Blinded, Palivizumab-Controlled Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of MK-1654 in Infants and Children at Increased Risk for Severe RSV Disease

Why is this study needed?

Researchers are looking for a way to prevent **RSV (Respiratory Syncytial Virus)** infection in infants. RSV is a common seasonal virus like the flu that causes runny nose, fever, cough, and wheezing (a whistling sound when breathing). Some infants are at increased risk of serious health problems from RSV, such as lung infections that need a hospital stay.

Palivizumab is a standard medicine to prevent RSV in babies who have increased risk of serious health problems from RSV. Palivizumab is given every month during **RSV season**, which often starts in the fall and goes until early spring. **Clesrovimab** (also known as MK-1654) is a study medicine designed to prevent RSV infections in infants. Clesrovimab is given one time during RSV season.

In this study, researchers want to learn about the safety of clesrovimab and how well it works to prevent RSV infection in infants compared to palivizumab.

Who will take part in this study?

About 1,000 infants ages newborn to 1 year who were born:

- At or before 35 weeks of pregnancy and are healthy **or**
- At or before 32 weeks of pregnancy and have a lung disease **or**
- With a heart disease

Infants in this study will not have had a vaccine or other medicine to prevent RSV.

What treatments are being given during the study?

Infants will get up to 2 of these treatments as an injection (shot) in the upper leg:

- **Palivizumab**, a standard medicine
- **Clesrovimab**, the study medicine
- **Placebo**, looks like the study medicine but has no medicine in it. Using a placebo helps researchers better understand the actual effects of the study medicine.

How is this study designed?

This study will have 2 parts. During **Part 1**, (the first 60 days of the study) parents or guardians and the researchers will not know which treatment infants get (called a **double-blind study**). During Part 2, they will know the treatment (called an **open-label study**). During Part 1, infants will join the study in the first RSV season after their birth. Infants will be assigned by equal chance to get either:

- Clesrovimab on study Day 1 (start of RSV season) and the placebo 1 month later
- Palivizumab on study Day 1 and again 1 month later

In the **open-label part,** infants who got palivizumab in Part 1 will get a dose of palivizumab every month for the rest of the 1st RSV season. Infants who got clesrovimab in Part 1 will not get more doses. About 300 infants and children from Part 1 will participate in a second RSV season in the study. During the 2nd RSV season, these infants and children will get 1 dose of clesrovimab. During

the study, researchers will take blood samples, do check-ups, and may do tests, including tests to know if a baby has RSV (by swabbing the inside of their nose).

An infant may be in the study for up to about one and a half 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 safety of clesrovimab and how well babies tolerate it compared to palivizumab	During the 1st RSV season, the number of children who have: • **Problems up to 5 days after getting each injection**, such as redness, swelling, and/or pain where the injection was given, fever, acting fussy, drowsy, or not as hungry as normal • **Any problems up to 42 days after getting the first injection**, including certain rashes and allergic reactions • **Serious adverse events (SAEs) that happen anytime.** SAEs are serious medical problems that happen or worsen during a clinical study.
Other goals	**How they will be measured**
To learn how well clesrovimab **works to prevent lung infections from RSV** that need health care visits compared to palivizumab	During the 1st RSV season, the number of infants who have both of these within 150 days (about 5 months) after getting the first injection: • Symptoms of a lung infection that needed a visit to a hospital, clinic, or doctor's office, **and** • A positive RSV test result, which means an infant has RSV
To learn how many children who get clesrovimab are **hospitalized due to RSV** compared to infants who get palivizumab	During the 1st RSV season, the number of infants who have both of these within 150 days after getting the first injection: • A hospital stay for a lung infection, **and** • A positive RSV test
To learn what happens to clesrovimab in an infant's body over time	During both RSV seasons, researchers will measure the amount of MK-1654 in blood samples at many time points
To learn about the safety of clesrovimab and how well babies tolerate it during the 2nd RSV season	During the 2nd RSV season, the number of children who have: • Problems up to 5 days after getting the injection • Any problems up to 42 days after getting the injection • SAEs that happen anytime

What are the possible benefits and risks?

Infants and children 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.