Protocol Plain Language Summary

Efficacy and safety of clesrovimab in healthy pre-term and full-term infants (MK-1654-004)

Protocol Title: A Phase 2b/3 Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-1654 in Healthy Pre-Term and Full-Term Infants

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 influenza (flu) that causes runny nose, fever, cough, and wheezing (a whistling sound when breathing) in people of any age. RSV infections spread easily among infants who are together in day care centres and can sometimes cause serious health problems, such as lung infections that require using health care, including hospital stays.

In this study, researchers want to learn about how well clesrovimab (also known as MK-1654) works to prevent RSV in healthy infants and how safe it is. Researchers also want to learn how infants react to clesrovimab after they get the medicine.

Who will take part in this study?

About 3,300 infants from birth to 12 months of age who:

- Were born pre-term (born at or after 29 weeks of pregnancy) or full-term
- Are healthy
- Are going into their first RSV season

How is this trial designed?

The parents or guardians of the infants and the researcher will not know which treatment each infant gets (called a **double-blind study**).

At certain times during the study, researchers will do check-ups and tests, including tests to know if an infant has RSV (by swabbing the nostrils). Researchers will check the infant's health for up to about 18 months.

What treatments are being given during the study?

Infants will be randomly assigned to receive either:

- **Clesrovimab**, the study medicine
- **Placebo**, a look-alike substance that does not contain any actual medicine. Using a placebo helps researchers better understand the actual effects of the study medicine.

Twice as many infants will receive clesrovimab. Both treatments are given once as a shot in the leg.

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

Main goals (Primary Objectives)	How they will be measured
To learn how well clesrovimab works to prevent lung infections from RSV that require health care visits, compared to the placebo	The number of infants who get lung infections from RSV that require health care within 150 days (about 5 months) after getting the shot, based on: • Signs of a lung infection that needed health care in the hospital, clinic, or doctor's office • A positive RSV test result, which shows an infant has RSV

To learn about the safety and tolerability of clesrovimab compared to placebo.	The number of infants who have one or more **adverse event (AE)**. AEs are medical problems that happen or worsen during a study. This includes:
	• **Problems up to 5 days after getting the shot**, such as:
	  ○ Fever
	  ○ Redness, swelling, or pain where the shot was given
	  ○ Acting fussy, drowsy, or not as hungry as normal
	• **Any problems up to 42 days after getting the shot**, including certain rashes and allergic reactions
	• **Serious AEs (SAEs) that happen anytime during the study.** SAEs are serious medical problems that happen or worsen during a clinical study

Other goals (Secondary Objectives)	How they will be measured
To learn how many infants who get clesrovimab are hospitalized due to RSV infection compared to infants who get placebo	The number of infants who have a hospital stay for lung infections and have a positive RSV test within 150 days after getting the shot
To learn how well clesrovimab works compared to placebo in infants with lung infection from RSV	The number of infants who get lung infections from RSV that require health care within 180 days after getting the shot, based on: • Signs of a lung infection that needed health care in the hospital, clinic, or doctor's office • A positive RSV test

What are the possible benefits and risks?

Infants may or may not benefit from the treatment received during the study. This study has a Data Monitoring Committee that oversees the study's overall risk and benefit. If this committee 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.