Short Trial Name:	Safety and Efficacy Trial of MK-1654 in Healthy Infants
Full Trial Name:	A Phase 2b/3 Double-Blind, Randomised, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-1654 in Healthy Pre-Term and Full-Term Infants
Protocol Number:	MK1654-004
EudraCT Number:	2020-002405-26
IRAS Number:	1003657

SUMMARY INFORMATION SHEET

We are inviting your child to take part in a clinical trial

- We would like to invite your child to take part in a clinical trial with the experimental drug MK-1654 which may prevent respiratory syncytial virus (RSV) infection.
- This information sheet summarises why the trial is being done and what is involved.
- Taking part in this trial is voluntary. It is up to you to decide whether or not you want your child to take part.
- If you decide to participate, you can then stop your child taking part in the trial at any time without giving a reason, by telling the trial doctor your decision.

How to contact us

If you have any questions about this trial, please contact the trial doctor at:

Dr Eva Galiza
Paediatric Infectious Disease office Rm LNS 5.063
St George's University Hospital NHS Foundation Trust
5th Floor, Lanesborough Wing,
Blackshaw Road,
London
020 8725 0293

1 What is the trial?

This trial is testing an experimental drug called MK-1654 in infants. MK-1654 is a type of antibody (called a "monoclonal antibody") being studied to see if it can prevent illnesses caused by the respiratory syncytial virus (RSV). An antibody is a protein naturally made in your child's blood that helps their immune system fight illnesses like viral infections. A monoclonal antibody is a protein made in a lab that acts like a human antibody. Monoclonal antibodies that target RSV work by blocking RSV from entering the body's cells.

What is RSV?

RSV is a common respiratory virus. It can cause cold-like symptoms, such as a runny nose, fever, and cough. Both adults and children can get RSV. Most healthy adults recover quickly from the virus. Sometimes, RSV causes serious health issues in infants,

such as breathing problems, high fever, and infections of the lungs.

RSV is one of the most common reasons that infants are taken to hospital and is the leading cause of hospitalisation and infant death under six months of age worldwide.

It is estimated that over 30,000 infants under 5 are hospitalised every year in the UK because of RSV and 6% of these will need admission to intensive care. Most of these admissions occur in infants who are otherwise healthy.

Currently, there are no treatments available in the UK to prevent RSV in healthy infants.

MK-1654 is an antibody (called "monoclonal antibody") designed to target RSV. By binding to the surface of the RSV, MK-1654 is intended to prevent RSV from infecting the infant's airways and causing disease.

This trial will compare MK-1654 to placebo. A placebo looks like a trial drug, but it has no active ingredients.

This trial is being done to:

- Test the safety of MK-1654 compared to placebo.
- See how well MK-1654 works to prevent RSV respiratory infections compared to placebo.

MK-1654 has not been approved for use in the UK and is not available by prescription. However, it is similar to an approved drug called palivizumab which is used to prevent RSV in infants with certain medical conditions.

Some infants will be in this trial for about 12 months and visit the trial site about 7 times. Others will be in the trial for about 18 months and visit the trial site about 8 times. Most visits will last about 1 – 2 hours.

This trial is being sponsored by the pharmaceutical company Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, New Jersey, USA ("MSD"). St George's University Hospitals NHS Foundation Trust will be paid by MSD for the costs associated with running this trial.

2 Who can be in this trial?

Healthy infants up to 8 months and 29 days of age can be in this trial.

There may be reasons why your child cannot be in this trial. The trial doctor or staff will discuss these reasons with you.

About 3,300 infants will take part in the trial from approximately 27 countries.

3 What drug will my child get?

The drug your child gets will depend on which group they are placed in. This trial has 2 treatment groups:

- **Group 1: will get MK-1654**
- **Group 2: will get placebo**

A computer will decide which group your child is put in. Your child has a 2 in 3 chance of getting MK-1654, and a 1 in 3 chance of getting placebo.

MK-1654 or placebo is given as an injection. The injection is given once only in the thigh. You, the trial doctor, and the trial staff won't know if your child was given MK-1654 or placebo. In case of a health emergency, they can find out.

If your child gets the placebo, it may look close to or exactly like MK-1654, but it does not contain any active ingredients.

Will I find out whether my child had MK1654 or placebo?

If you wish to know what drug your child was given you should ask the trial doctor, but they will not be able to give you this information until approx. 6 months after the trial has completed.

4 Expenses and payments

All trial medication and trial-related tests will be provided at no cost to you. You will be paid a stipend payment for your child to participate in the trial.

You will receive a stipend payment of £30.00 for each of your child's clinic visits.

Stipend payments are offered as recompense to help cover the cost of any associated expenses, (which may include such things as child-care, time off from work for clinic visits etc.).

You will be reimbursed for your transportation, parking, meals, or other reasonable expenses related to your participation in this trial. If you withdraw your child from the trial early, you will be reimbursed for these expenses for the portion of the trial that your child completed.

5 How will my child's privacy be protected?

The trial team and Sponsor have strict privacy and confidentiality policies in place to protect your child's information. The Sponsor will ensure adequate safeguards are in place to protect your child's data and abide by UK data privacy laws. Information about your child will be collected and shared as described in the main participant information sheet, which will be given to you if you would like more information about the trial.

6 What happens next?

If you would like further details on this trial, please contact the trial doctor whose contact details are in the "How to contact us" section at the beginning of this document. If you wish to consider for your child to take part in the trial, you must read and sign the main participant information sheet and consent form.

Thank you for reading this information sheet.

Use this space to note down any questions you may want to ask your doctor.