Protocol Plain Language Summary

A clinical study of ertugliflozin in children with diabetes (MK-8835-059)

Protocol title: A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled Clinical Study to Evaluate the Safety and Efficacy of Ertugliflozin (MK-8835/PF-04971729) in Pediatric Participants (ages 10 to 17 years, inclusive) with Type 2 Diabetes Mellitus

Why is this study needed?

Researchers are looking for new treatments for children with **type 2 diabetes (T2D)**. T2D is a chronic (long-lasting) condition in which a person's blood sugar (also called blood glucose) levels are too high because the body does not make enough insulin or doesn't use the insulin well.

Standard treatments for children with T2D include **metformin** (a medicine taken by mouth) alone or with **insulin** (a treatment given by injection). These treatments may not work well enough to control blood sugar, or children may have trouble taking metformin or insulin every day.

Ertugliflozin is a drug used to treat adults with T2D. The purpose of this study is to learn if adding ertugliflozin to standard treatment is safe and works better to lower blood sugar than adding placebo to standard treatment, in children with T2D. A placebo looks like the study medicine but does not contain any active medicine. Using a placebo helps researchers better understand the effects of the study medicine.

Who will take part in this study?

About 165 children with T2D will take part in this study. They will be 10 to 17 years old and:

- Currently take standard treatment for T2D (metformin alone or with insulin)
- Have blood sugar that is not well managed
- Not have type 1 diabetes

How is this study designed?

This study has 2 treatment groups. Children will be assigned by chance to Group 1 or Group 2:

- **Group 1** will take the **study medicine ertugliflozin**
- **Group 2** will take a **placebo**

Twice as many children will be in Group 1 than Group 2. Children in both groups will continue to take their current standard treatment (metformin alone or with insulin). Children will take ertugliflozin or placebo by mouth as pills once a day for about a year.

Neither the children in the study nor the researcher will know which treatment the child is taking (double-blind study).

Each child will be in this study for about 14 months. Children will give urine and blood samples and have physical examinations and imaging tests during the study. Children or their caregivers will check the child's blood sugar levels at home with a finger stick.

What treatments are being given during this study?

During this study, children will take either ertugliflozin or placebo by mouth along with their current standard treatment (metformin alone or with insulin) for T2D.
Every child assigned ertugliflozin will get a **lower dose** each day for the first 3 months of treatment. Then, some children assigned ertugliflozin may start to get a **higher dose.**

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

Main goals	How they will be measured
To compare **blood sugar levels** in children who take ertugliflozin to children who take placebo	Change in **A1c** from start of the study to Week 24. A1c is a measure of how much sugar is in the blood over the past 3 months.
To learn about **safety** and how well children tolerate ertugliflozin	By Week 24 and Week 54, the number of children 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

Other goals	How they will be measured
To compare blood sugar levels in children who switch to the higher dose of ertugliflozin to children who take placebo	Change in A1c from start of the study to Week 24
To compare blood sugar levels in children who stay on the lower dose of ertugliflozin to children who take placebo	Change in A1c from start of the study to Week 24
To learn if there is a change in **fasting plasma glucose** (**FPG**). FPG measures blood sugar levels after not eating or drinking for at least 10 hours.	Change in FPG from start of the study to Week 24 and Week 54
To learn if there is a change in blood sugar levels	Change in A1c from start of the study to Week 54

What are the possible benefits and risks?

Clinical studies have benefits and risks. Children may benefit because the study medicine may treat T2D or stop it from getting worse. There may be risks because the study medicine may not work or may cause health problems. This study has a group of experts, separate from the researchers, who oversee the benefits and risks. If they decide that the study treatment is not safe or does not show benefit, the study can be stopped.

More information about benefits and risks is in the protocol.