Information for Eligible Participants

Purpose of the Study

The purpose of the VX22-264-101 Study is to learn more about how safe, tolerable, and effective an investigational cell-based therapy, called VX-264, is in adults with type 1 diabetes (T1D). VX-264 consists of cells designed to produce insulin contained within devices designed to protect the cells from the immune system.

What to Expect

Before you can take part in this study, the study staff will review an informed consent form (ICF) and you will be asked to sign it, confirming that you have been informed of the details of the study and agree to participate. You will then need to attend screening visit(s) to complete initial tests and assessments to see if you are eligible to participate. If you are considered eligible to participate after screening, you may be able to enter the study and receive VX-264.

If you are considered eligible, you will receive all study-related medications and procedures at no cost. You and your study doctor may choose to have some of the study visits conducted at your home with a home health nurse, allowing for a reduced number of times that you must travel to the study site. You may also be compensated financially for your study-related time and reimbursed for travel.

About VX-264

The standard treatment for T1D is insulin given by multiple daily injections or a pump. However, this treatment does not always sufficiently control blood sugar levels. This is one of the reasons why research studies like the VX22-264-101 Study are being performed to evaluate potential treatments and therapies.

VX-264 is comprised of cells designed to produce insulin contained within devices designed to protect these cells from the body's immune system. These investigational devices are implanted in the space behind the muscles of the abdominal wall in a surgical procedure under general anesthesia. Also under study are the containers that hold VX-264 prior to surgery and the specialized tools used to surgically implant VX-264. All of these are investigational.

About the Investigational Device Implant

If you qualify to participate in the study, you will be admitted to the hospital for three or four days to have VX-264 implanted.

Study Participation

The total length of study participation is approximately five years. After the prescreening and screening periods, eligible participants will enter the treatment period and have VX-264 implanted. During this period, a consecutive overnight stay of three to four nights at the clinical research site will be required. The follow-up period will last approximately five years.

Study Eligibility

Eligible participants must meet the following criteria:

- Be between the ages of 18 and 65 (inclusive)
- Have had insulin-treated T1D for at least five years
- Have blood type A or AB
- NOT have had an islet cell transplant, an organ transplant, or cell therapy
- NOT have advanced complications associated with diabetes, including untreated advanced diabetic retinopathy, diabetic nephropathy, skin ulcers, or amputations attributable to diabetes

There are additional eligibility requirements, which the study doctor will discuss with those interested in participating.

Thank you for your interest in the VX22-264-101 Study.