Title:

A phase 1/2 study to evaluate the safety, tolerability, and efficacy of VX-880 in subjects who have type 1 diabetes mellitus with impaired hypoglycemic awareness and severe hypoglycemia

Principal Investigators:

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Institutions:

UHN/Toronto General Hospital
McGill University Health Centre

Description of study:

The purpose of this study is to evaluate the safety, tolerability, and efficacy of an investigational islet cell infusion in individuals with type 1 diabetes with episodes of severe low blood sugar (hypoglycemia) and impaired hypoglycemic awareness. The goal of this infusion is to provide replacement cells for the ones that have been lost or do not work properly in people with diabetes.

The infusion of islet cells will occur up to 90 days after the screening visit. Prior to a planned islet cell infusion, you will be admitted to the hospital for approximately three days and will remain in the hospital for approximately four more days after the infusion for safety monitoring. There may be a second infusion if you are enrolled in the first part of the study. The follow-up period is approximately five years following your final infusion. After these initial five years, you may be asked to participate in a separate long-term follow-up study.

During the study:

- You will need to attend follow-up visits monthly after the infusion for the first year and about every three months after for approximately five years. You and your study doctor may choose to have some of the study visits at your home with a home health nurse.
- You will receive several medicines before, during, and after the infusion of the islet cells and will be asked to take medicines for the entire duration of the study.
- You must wear the study CGM which will be provided to you at no cost.

Funding Source:

Vertex Pharmaceuticals Inc.

Project Start Date:

March 29, 2021

Project End Date:

July 7, 2028

Eligibility:

Key Inclusion Criteria:

- 18 years to 65 years of age
- Clinical history of T1D with > 5 years of duration
- At least two episodes of documented severe hypoglycemia requiring assistance from somebody else to recover in the 12 months prior to enrollment
- Stable diabetic treatment
- Blood type of A or AB
- Consistent use of continuous glucose monitor (CGM) for at least 3 months before Screening and willingness to use CGM for the duration of the study

Key Exclusion Criteria:

- Prior islet cell transplant, organ transplant, or cell therapy
- Advanced complications associated with diabetes, including untreated proliferative retinopathy, skin ulcers, or amputations attributable to diabetes
- Significant active infection or chronic infection such as hepatitis B or C, HIV, tuberculosis, invasive aspergillus, histoplasmosis, or coccidioidomycosis within the past year

Ethics Approval:

Approved by UHN REB, McGill REB, Advarra Canada

Contact

If you would like to participate in this study, please contact:

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