Dear Patient,

I’m writing to inform you of a new clinical research study of an investigational infusion in individuals who have been diagnosed with type 1 diabetes with severe low blood sugar (hypoglycemia) and impaired hypoglycemic awareness. My office is conducting this study, along with other qualified and well-trained clinical research study doctors in locations around the United States. This letter is intended to share information about the study with you so that you can consider participation.

The purpose of this type 1 diabetes study is to evaluate the safety, tolerability, and effectiveness of an investigational islet cell infusion called VX-880. The word “investigational” means this medication is not yet approved for use by the Food and Drug Administration (FDA) in the United States or other regulatory agencies in Canada, Europe, or elsewhere. The goal of this infusion is to provide replacement cells for the ones that have been lost or don’t work properly in people with diabetes.

Eligible participants must meet the following key criteria:

- Male or female between the ages of 18 and 65 (inclusive)
- Diagnosed with type 1 diabetes with documented severe hypoglycemia and impaired hypoglycemic awareness
- Blood type A or AB
- Do not have significant active infection or chronic infection such as hepatitis B or C, HIV, tuberculosis, invasive aspergillus, histoplasmosis, or coccidioidomycosis within the past year
- Do not have advanced complications associated with diabetes including untreated proliferative retinopathy, skin ulcers, or amputations attributable to diabetes
- Consistent use of a continuous glucose monitor (CGM) for the last three months
- Willing and able to comply with the study instructions

There are additional eligibility requirements, which the study doctor will explain to you. If you qualify, 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 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.

If you are interested in learning more about this study, visit www.pwitkowski.org/vertex or contact Clinical Study Manager Lindsay Basto at Lindsay.Basto@uchospitals.edu or call 773-702-2504. Lindsay will tell you more about the study, including any risks and benefits of participation.

Thank you for considering this type 1 diabetes clinical research study.

Sincerely,

John Fung, MD PhD