Supplementary Data

Inclusion and Exclusion Criteria

General inclusion criteria

(1) Subject is aged 14–75 years at time of screening.
(2) Subject has a clinical diagnosis of type 1 diabetes for 2 years or more as determined via medical records or source documentation by an individual qualified to make a medical diagnosis.

Study-specific inclusion criteria

(1) Subject is willing to participate in a hotel study for the specified duration of hotel stay.
(2) Subject must have a companion who will sleep in the same dwelling place every night during the study period and should also be able to call the subject daily in the event the subject is traveling. This requirement may be verified by subject report at screening visit.
(3) Subject is willing to perform ≥4 finger stick blood glucose measurements daily.
(4) Subject is willing to perform required sensor calibrations.
(5) Subject is willing to wear the system continuously throughout the study.
(6) Subject has a glycosylated hemoglobin (HbA1c) value less than 10.0% at time of screening visit.
(7) Subject has Thyroid Stimulating Hormone (TSH) in the normal range odds ratio, if the TSH is out of normal reference range the Free T3 is below or within the laboratory's reference range and Free T4 is within the normal reference range.
(8) Pump therapy for greater than 6 months before screening (with or without CGM experience).
(9) Subject is willing to upload data from the study pump and must have Internet access and a computer system that meets the requirements for uploading the study pump.
(10) If subject has celiac disease, it has been adequately treated as determined by the investigator.
(11) Subject is willing to take one of the following insulins and can financially support the use of either of the two insulin preparations throughout the course of the study (i.e., copayments for insulin with insurance or able to pay full amount).
  (a) Humalog® (insulin lispro injection)
  (b) NovoLog® (insulin aspart)
(12) Subjects with history of cardiovascular event 1 year or more from the time of screening must have an electrocardiogram (EKG) within 6 months before screening or during screening. If subject has an abnormal EKG, participation is allowed if there is clearance from a cardiologist.
(13) Subjects with the 3 or more cardiovascular risk factors listed below must have an EKG within 6 months before screening or during screening. If subject has an abnormal EKG, participation is allowed if there is clearance from a cardiologist. Cardiovascular risk factors include the following:
  (a) Age >35 years
  (b) Type 1 diabetes of >15 years of duration
  (c) Presence of any additional risk factor for coronary artery disease
  (d) Presence of microvascular disease (proliferative retinopathy or nephropathy, including microalbuminuria)
  (e) Presence of peripheral vascular disease
  (f) Presence of autonomic neuropathy
(14) Subjects with history of cardiovascular event 1 year or more from the time of screening must have a stress test within 6 months before screening or during run-in period. If subject fails the stress test, participation is allowed if there is clearance from a cardiologist.
(15) Subjects must be able to speak and be literate in English.

Exclusion criteria

(1) Subject has a history of two or more episodes of severe hypoglycemia, which resulted in any of the following during the 6 months before screening:
  (a) Medical assistance (i.e., paramedics, emergency room [ER], or hospitalization)
  (b) Coma
  (c) Seizures
(2) Subject is unable to tolerate tape adhesive in the area of sensor placement.
(3) Subject has any unresolved adverse skin condition in the area of sensor placement (e.g., psoriasis, dermatitis herpetiformis, rash, staphylococcus infection).
(4) Females who are sexually active and able to conceive will be excluded if they are not using an effective method of contraception and do not agree to continue using an effective method of contraception for the duration of the study as determined by investigator.
(5) Subject has had any of the following cardiovascular events within 1 year of screening: myocardial infarction, unstable angina, coronary artery bypass surgery, coronary artery stenting, transient ischemic attack, cerebrovascular accident, angina, congestive heart failure, ventricular rhythm disturbances, or thromboembolic disease.
(6) Subject is being treated for hyperthyroidism at time of screening.
(7) Subject has diagnosis of adrenal insufficiency.
(8) Subject has had DKA in the 6 months before screening visit.
(9) Subject has taken any oral, injectable, or intravenous (IV) steroids within 8 weeks from time of screening visit, or plans to take any oral, injectable, or IV steroids during the course of the study.
(10) Subject is actively participating in an investigational study (drug or device), in which he or she has received treatment from an investigational study drug or investigational study device in the last 2 weeks.

(11) Subject has been hospitalized or has visited the ER in the 6 months before screening resulting in a primary diagnosis of uncontrolled diabetes.
(12) Subject is currently abusing illicit drugs.
(13) Subject is currently abusing marijuana.
(14) Subject is currently abusing prescription drugs.
(15) Subject is currently abusing alcohol.
(16) Subject is using pramlintide (Symlin), DPP-4 inhibitor, liraglutide (Victoza or other GLP-1 agonists), metformin, canagliflozin (Invokana or other SGLT2 inhibitors) at time of screening.
(17) Subject has a history of visual impairment, which would not allow subject to participate in the study and perform all study procedures safely, as determined by the investigator.
(18) Subject has elective surgery planned that requires general anesthesia during the course of the study.
(19) Subject has a sickle cell disease, hemoglobinopathy, or has received red blood cell transfusion or erythropoietin within 3 months before time of screening.
(20) Subject plans to receive red blood cell transfusion or erythropoietin over the course of study participation.
(21) Subject diagnosed with current eating disorder such as anorexia or bulimia.
(22) Subject has been diagnosed with chronic kidney disease that results in chronic anemia.
(23) Subject has a hematocrit that is below the normal reference range of laboratory used.
(24) Subject is on dialysis.
(25) Subject has serum creatinine of >2 mg/dL.