Inclusion/Exclusion Criteria

Inclusion Participants are eligible to be included in the study only if all of the following criteria apply:		
1	Male and female participants aged 18 years or older at screening (Visit 1)	YES NO
2	T1DM or T2DM of at least 5 years' duration, with controlled and stable blood glucose levels (ie, no episodes of diabetic ketoacidosis, Hyperosmolar Hyperglycemic Nonketotic Diabetic Syndrome, or severe hypoglycemia within the 6 months preceding screening [Visit 1])	YES NO
3	HbA1c ≤11.0% at screening (Visit 1) in participants being treated for at least 3 months with oral and/or parenteral medications for T1DM or T2DM with the goal of achieving controlled and stable glucose levels	YES NO
4	DG defined as at least a 3-month history prior to screening (Visit 1) of symptoms on an ongoing basis that are suggestive of GP (eg, nausea, abdominal pain, post-prandial fullness, bloating, vomiting, and early satiety)	YES NO N/A
5	Female participants willing to minimize the risk of inducing pregnancy for the duration of the clinical study and follow-up period A female participant is eligible to participate if she is not pregnant (has a negative urine pregnancy result prior to randomization; see Appendix 5), not breastfeeding, and at least one of the following conditions applies: a. Not a woman of childbearing potential (WOCBP) as defined in Appendix 5 OR b. A WOCBP who agrees to follow the contraceptive guidance in Appendix 5 during the treatment period and for at least 7 days after the last dose of study treatment	YES NO
6	Documentation of absence of an obstructing lesion on upper endoscopy or other equivalent diagnostic test, performed at some time before screening (Visit 1) but after the appearance of symptoms that led to the diagnosis of DG	YES NO
7	At least 2 vomiting episodes during the 2 weeks prior to screening (Visit 1), as ascertained by participant history	YES NO
8	Delayed GE confirmed by abnormal GEBT, defined as GE half-time ($t_{½}$) ≥ 79 minutes at the start of the placebo-controlled Run-in Period (Visit 2). In countries where the GEBT is not available, delayed GE may be confirmed by abnormal scintigraphy result (> 60% retention at 2 hours or > 10% at 4 hours). Refer to the Study Reference Manual	YES NO
9	BMI > 18.5 kg/m_2 and < 35.0 kg/m_2	YES NO
10	Able to provide written informed consent (IC) prior to any study procedures and willing and able to comply with study procedures	YES NO

Inclusion/Exclusion Criteria

Inclusion Criteria cont'd… *Additional inclusion criteria for randomization after the 2-week, placebo Run-in Period:*		
11	Compliance with the entry of data into the hand-held electronic device on at least 10 of 14 days during the placebo Run-in Period	YES NO
12	Compliance with administration of SC twice daily injections, as evidenced by entries made by the participant using the electronic, hand-held device on at least 10 of 14 days during the placebo Run-in Period	YES NO
13	At least one vomiting episode at any time during the placebo Run-in Period, as recorded in the DGSSD, using the electronic hand-held device	YES NO
14	The average of the daily DGSSS from the 2-week, placebo Run-in Period must be ≥ 16	YES NO

Exclusion Criteria Participants are excluded from the study if any of the following criteria apply:		
1	Symptomatic Irritable Bowel Syndrome at Screening (Visit 1)	YES NO
2	Small intestinal bacterial overgrowth (SIBO) at Screening (Visit 1)	YES NO
3	History of anorexia nervosa, binge-eating, bulimia, or other eating disorder within 5 years of screening (Visit 1)	YES NO
4	History of intestinal malabsorption (including celiac disease even if participant adheres to a gluten-free diet) or pancreatic exocrine insufficiency	YES NO
5	History of functional dyspepsia, belching disorders, other nausea and vomiting disorders (eg, chronic nausea and vomiting syndrome, cyclic vomiting syndrome, cannabinoid hyperemesis syndrome), or rumination syndrome	YES NO
6	Presence of anemia, defined as a hemoglobin value on the complete blood count (CBC) done at screening (Visit 1) of < 11.0 g/dL (110 g/L) in males and < 10.0 g/dL (100 g/L) in females	YES NO
7	Evidence of hepatic disease defined as alanine aminotransferase (ALT) or aspartate aminotransferase (AST) ≥ 3 x ULN, and/or direct bilirubin ≥ 2 x ULN	YES NO
8	History of malignancy in the 5 years prior to Visit 1, except for adequately treated basal cell or squamous cell skin cancer, or in situ cervical cancer	YES NO
9	Currently receiving parenteral feeding or presence of a nasogastric or other enteral tube for feeding or decompression	YES NO

Inclusion/Exclusion Criteria

10	Use of metoclopramide, domperidone, prucalopride, macrolide antibiotics (eg, azithromycin, clarithromycin, erythromycin), or other drugs considered to be GI promotility agents (Table 7-2) for at least 2 weeks prior to the start of the Run-in Period (Visit 2)	YES NO
11	Abuse of drugs (eg, amphetamines, barbiturates, benzodiazepines, cocaine, cannabinoids, opiates, and phencyclidine). Urine drug screening will be conducted at Visit 1. Clinical significance of a positive urine drug screen will be assessed by the investigator. Positive results on the urine drug screen will exclude participants from participating in the study. Use of opiates for any reason is prohibited during the study	YES NO
12	Currently taking opiates, or expecting to use opiates during the course of the clinical study	YES NO
13	Treatment with glucagon-like peptide-1(GLP-1) agonist or pramlintide for at least 2 weeks prior to the start of the Run-in Period (Visit 2)	YES NO
14	History of pyloric injection of botulinum toxin within 6 months of screening	YES NO
15	History of gastric surgery such as fundoplication, gastrectomy, gastric pacemaker placement, vagotomy, or bariatric procedure (a history of diagnostic endoscopy is not exclusionary)	YES NO
16	Participation in any previous study in which relamorelin was a treatment	YES NO
17	Estimated glomerular filtration rate (eGFR) of < 30 mL/min	YES NO
18	Current enrollment in an investigational drug or device study or participation in such a study within 30 days of entry into this study	YES NO
19	Allergic to, or intolerant of egg, wheat, milk, or algae, as these are components of the GEBT study meal (gluten-free crackers can be provided)	YES NO
20	Females who are pregnant, nursing, or planning a pregnancy during the study. For females who are of childbearing potential, see Appendix 5	YES NO

Inclusion/Exclusion Verification

By signing below I verify that all Inclusion/Exclusion Criteria has been reviewed and met by the subject. I certify that the subject is eligible to be enrolled in the study.

PI Signature and date: _____

Inclusion/Exclusion Criteria

Study Coordinator Signature and date: _____