Call Toll-free 1-800 856-7842 or 828-254-0881 with Extension listed

Name of Study: **A 12-Week Study with a 4-Week Randomized Withdrawal Period to Evaluate the Efficacy and Safety of Tenapanor for the Treatment of IBS-C (T3MPO-1)- (Ardelyx Pharmaceuticals)**

PI: Brian Garvin, MD

LINK: https://clinicaltrials.gov/ct2/show/NCT02621892?term=Ardelyx+IBS&rank=3

Study Coordinator: Kylee Diaz x **3426** or Direct-828-350-3669

Enrollment Starts: May 2016

Enrollment Ends: December 2016

Summary: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Tenapanor for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)

Inclusion:

- Age: 18-75 years (Females of CBP and males with partners of CBP must use 2 forms of birth control)
- Subject meets definition of IBS-C using Rome III Criteria for the Diagnosis of IBS
- Subject meets screening eligibility criteria (see below)
    - A colonoscopy based on AGA guidelines; every 10 years at ≥ 50 years old, or the occurrence of any warning signs (i.e., unexplained weight loss, non-hemorrhoid blood in stools)
    - Ability to communicate well with the Investigator and to comply with the requirements of the entire study, including an understanding of how to use the touch-tone telephone electronic diary.
    - Written informed consent and a willingness to participate in the study as it is described.
    - Daily access to a touch tone telephone.

Exclusion:

- Functional diarrhea as defined by Rome III criteria
- IBS with diarrhea (IBS-D), mixed IBS (IBS-M), or unsubtyped IBS as defined by Rome III criteria

- Diagnosis or treatment of any clinically symptomatic biochemical or structural abnormality of the GI tract within 6 months prior to screening, or active disease within 6 months prior to screening; including but not limited to cancer, inflammatory bowel disease, diverticulitis, duodenal ulcer, erosive esophagitis, gastric ulcer, pancreatitis (within 12 months of screening), cholelithiasis, amyloidosis, ileus, non-controlled GERD, gastrointestinal obstruction, ischemic colitis or carcinoid syndrome.
- Subject has a potential CNS cause of constipation (e.g., Parkinson's disease, spinal cord injury, or multiple sclerosis)
- Use of medications that are known to affect stool consistency (Prohibited Medications), including fiber supplements, anti-diarrheals, cathartics, antacids, opiates, prokinetic drugs, laxatives, enemas, antibiotics during the screening period; unless specified as rescue medication, and used accordingly
- Patients on a stable, continuous regimen of fiber, bulk laxatives, stool softeners, or probiotics for the 30 days prior to the screening visit are allowed, provided they agree to maintain a stable regimen throughout the trial
- Subject has a history or current evidence of laxative abuse (in the clinical judgment of the physician)
- Hepatic dysfunction (ALT [SGPT] or AST [SGOT] >2.5 times the upper limit of normal) or renal impairment(serum creatinine > 2mg/dL)
- Any evidence of or treatment of malignancy (other than localized basal cell, squamous cell skin cancer or cancer insitu that has been resected) within the previous year
- Any surgery on the stomach, small intestine or colon, excluding appendectomy or cholecystectomy (unless within 60 days of screening visit)
- Pregnant or lactating women
- A major psychiatric disorder (DSM-III-R or DSM-IV) including major depression or other psychoses that has required hospitalization in the last 3 years. History of attempted suicide or uncontrolled bipolar disorder
- Alcohol or substance abuse in the last year
- Participation in other clinical trials within 1 month prior to Day –14 (beginning of screening period)
- Clinical evidence of significant cardiovascular, respiratory, renal, hepatic, gastrointestinal, hematologic, neurologic, psychiatric or any disease that may interfere with the subject successfully completing the trial
- Subject has been randomized into any Phase 1 or 2 study in which Tenapanor was a treatment
- Subject is involved in the conduct and/or administration of this trial as an investigator, subinvestigator, trial coordinator, or other staff member, or the subject is a first degree family member, significant other, or relative residing with one of the above persons involved in the trial
- If, in the opinion of the Investigator the subject is unable or unwilling to fulfill the requirements of the protocol or has a condition, which would render the results uninterpretable