

## Research Objectives for Investigator-Sponsored Study Submissions

Solvay Pharmaceuticals, Inc., considers the following when evaluating proposals for scientific/clinical research

### **Men's Health Investigator-Sponsored Studies (ISS)**

- Diagnosis of Symptomatic Low Testosterone
  - Predictive value of:
    - Waist Circumference
    - Fatigue
    - Other Signs and Symptoms
  - Prevalence in Patients with Comorbid Conditions
    - Chronic Opioid Use
    - Men Treated for Depression
    - Iatrogenic Causes
    - Other
- Testosterone Therapy related to:
  - Outcomes Associated with Difference in Delivery (i.e., Safety, Clinical, Quality of Life, Health Economics, Compliance, Treatment Satisfaction)
  - Cardiovascular System
    - Congestive Heart Failure – Functional Outcomes
  - Cognitive Function
  - Neurodegenerative Diseases
  - Prostate
    - Surrogate Markers for Safety
  - Sexual Function
    - Satisfaction
  - Effects of Weight Loss on Hypogonadal Men
- Factors Affecting TRT Dosing
  - Androgen Receptor Polymorphism
  - BMI
  - Hypogonadal Obese Men
  - Other
- Pharmacoeconomic and Health Outcome Measurements of Symptomatic Low Testosterone and/or Testosterone Replacement Therapy

### **Gastroenterology Investigator-Sponsored Studies (ISS)**

- Exocrine Pancreatic Insufficiency (EPI) related to:
  - Pancreatic Cancer
  - Celiac Disease
  - Gastric Bypass Surgery
  - Diabetes as it relates to EPI
  - Cystic Fibrosis (CF)
  - Chronic Pancreatitis (CP)
  - Irritable Bowel Syndrome (IBS)
  - Pancreatectomy
  - HIV Infection/Anti-retroviral Therapy
  - Acute Pancreatitis
  - Tube Feedings
- Tools to aid in the diagnosis, evaluation and treatment of EPI
- Nutritional status of CP patients
- Pancreatic enzyme dosing for EPI
- Additional areas of interest include:
  - Epidemiological
  - Surrogate Endpoints
  - Outcomes Data
  - Food Allergies
  - Pancreatic Diseases
  - Maldigestion Syndromes

**Please note that we will not review research proposals that duplicate existing ISS or Solvay protocols**