Please contact the Research Office if you're interested in any of the following clinical trials:
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BOOM-IBD2 Pivotal Trial- Sacral Nerve Stimulation (SNS) treatment for Ulcerative Colitis (UC)

PI: Marco Zoccali, MD
IRB: AAAV4351
Disease: **Ulcerative Colitis (UC)**

The purpose of this study is to evaluate the safety and effectiveness of SNS in study participants who have UC. SNS is a minimally invasive, outpatient procedure performed under conscious sedation. The neurostimulator device with leads stimulates the sacral nerve by delivering electrical impulses to the nerves in the pelvis. While the investigational medical device used in this research study has been studied and approved by the FDA to treat overactive bladder and fecal incontinence, its use in this study for the treatment of UC is investigational. If you decide to participate in this study, you will be one of up to 25 subjects at Columbia University Irving Medical Center (CUIMC). Your participation in this study will be approximately 1 year long.

Eligibility:

1. 18 to 85 years of age, diagnosed with UC for more than 3 months
2. Experience bowel urgency
3. Tried less than four advanced therapies (biologics and/or small molecules) for UC
4. No changes in advanced therapies within 120 days prior to the research procedure.

AXONICS: Sacral Neuromodulation (SNM) therapy for people who have Overactive Bladder (OAB) and/or Fecal Incontinence (FI).

PI: Marco Zoccali, MD
IRB: AAAV3913
Disease: **Fecal Incontinence**

The purpose of this study is to evaluate the safety and effectiveness of a device called the Axonics SNM System in reducing symptoms for people who have Overactive Bladder (OAB) and/or Fecal Incontinence (FI). The study will enroll up to 130 participants at up to 20 sites in the United States and Western Europe. The Axonics System delivers mild electric pulses (stimulation) to the area of the sacral nerve, which is located in the lower back. This Sacral Neuromodulation (SNM) therapy treats bladder and bowel dysfunction such as urinary urgency incontinence (UUI), urinary frequency (UF) and fecal incontinence (FI). This therapy is expected to lower your symptoms and improve your day-to-day life. The device and procedure are both approved by the United States Food and Drug Administration. The F15 device (Model 4101) is a non-rechargeable device, which means it does not need charging. The non-rechargeable F15 device is approved to be used in the United States and Canada but not yet in Europe. This trial is being conducted to collect additional information for the non-rechargeable F15 device for approval in Europe. If you decide to participate in this study, you will be one of the subjects at Columbia University Irving Medical Center (CUIMC), who will receive a medical device to control your bowel symptoms. CUIMC does not treat patients with OAB and urinary incontinence symptoms in this clinical trial. You will return to your doctor's office for several follow-up visits after your standard of care device implant. They are scheduled at 1 month, 3 months, 6 months, 9 months (phone call only) and 1 year.

Eligibility:

1. Chronic Fecal Incontinence who are not candidates for or who have failed conservative treatment
2. Not previously implanted with a sacral neuromodulation device

DB-3Q: Bone marrow mesenchymal stem cell (bmMSC) derived extracellular vesicles product in Patients with Perianal Fistulizing Crohn's Disease (CD)

PI: Marco Zoccali, MD
IRB: AAAV6645
Disease: **Perianal Fistulas** due to Crohn's Disease (CD)

Treatment: DB-3Q (a bone-marrow mesenchymal stem cell product) or Placebo

The purpose of this study is to evaluate the efficacy and safety of ascending doses of DB-3Q, a bone-marrow mesenchymal stem cell (bmMSC) derived secretome with extracellular vesicles (EVs) isolate product, via direct injection and intravenous (IV) administration, as treatment for participants with perianal fistulizing Crohn's disease (PFCD). The investigational product is experimental and has not been approved by the US Food and Drug Administration (FDA). The experimental study drug is a biologic product which is purified from the bone marrow of a healthy well-screened individual.

36 participants with perianal fistulizing Crohn's disease, randomized 3:1 to IMP or placebo in blocks of 4 participants (3 randomized to IMP, and 1 randomized to placebo) such that each cohort will have 12 participants (9 randomized to IMP and 3 randomized to placebo).

Your participation in this study will be approximately 24 weeks long.

Eligibility:

1. 18-75 years of age with a diagnosis of Crohn's Disease for at least six months duration prior to Day 1
2. Single and/or multi-tract perianal fistula(s) with 2 or fewer openings, that are actively draining
3. Failed at least one medical therapy within the last year
4. Previous failed surgical intervention or not interested in surgical intervention
5. NO ileal anal pouch and/or history of proctectomy and severe proctitis

PATENT-B - Paclitaxel Coated Balloon for the Treatment of Chronic Benign Stricture- Bowel

PI: Bo Shen, MD
IRB: AAAU3865
Disease: **Ulcerative Colitis (UC) and Crohn's Disease (CD)**

The purpose of this study is to evaluate the safety and efficacy of GIE Medical's ProTractX3™ TTS DCB for the treatment of recurrent benign bowel strictures. This study is conducted to see whether this new drug coated balloon dilation device can treat strictures and reduce the rate of recurrence. Up to 215 subjects will participate in the main study at up to 30 sites in the United States.

Participants in the study will be randomly assigned to receive study treatment with either the ProTractX3 DCB (study device), or a normal dilation. You are two times as likely to be randomly chosen to receive study treatment with the study device compared to the standard of care (2:1 randomization).

The treatment procedure may be done on the same day as your screening, or it might be done several days after. After study treatment, you are required to return to the clinic for four (4) follow-up visits in the first year (1, 3, 6 & 12 months) and one visit each year after that for eight visits after study treatment (up to 5 years).

Eligibility:

1. Age ≥ 22
2. Diagnosis of symptomatic benign bowel stricture with at least 2 previous dilations.
3. Stricture length ≤ 5 cm, and not complicated with abscess, fistula, perforation, leakage or varices
4. Agrees to attend all follow-up assessments for up to 5 years

AFFIRM: Abbvie Study M23-748: A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Efficacy and Safety of **Risankizumab Subcutaneous** Induction Treatment in Subjects with Moderately to Severely Active **Crohn's Disease**

PI: Le-Chu Su, MD
IRB: AAAV0516
Disease: **Crohn's Disease**
Treatment: **Risankizumab** Subcutaneous **(SKYRIZI®)**

The purpose is to see if **Risankizumab (RZB) given as a subcutaneous injection** (SC injection into the deepest skin layer) to induce remission (induction therapy) is safe and works well to treat moderate to severe Crohn's disease (CD). Risankizumab is approved by the United States Food and Drug Administration (FDA) for moderately to severely active Crohn's disease given as an intravenous induction followed by risankizumab given subcutaneously to maintain therapy. Therefore, the use of the study drug is investigational (experimental) for the purposes of this study as a subcutaneous induction followed by subcutaneous maintenance therapy. Participants will be randomized in a 2:1 ratio to RZB or placebo arm. The study will enroll up to 276 participants at up to 250 sites. Your participation in this study will be approximately 93 weeks.

The study includes up to a 5-week screening period, followed by a primary treatment period consisting of Period A (Weeks 0-12), Period B (Weeks 12-24), a 52 open label extension (OLE) Period C (Weeks 24-76), and a 20-week follow up visit/call after the last dose of study drug.

Eligibility:

1. Age ≥ 18
2. Moderately to severely active CD, who have intolerance or inadequate response to conventional therapies and/or advanced therapies (e.g., biologics, targeted small molecules) for CD.

HORIZON: Abbvie Study M23-703: A Phase 2b Multicenter, Randomized Study to Evaluate the Safety and Efficacy of **Lutikizumab for Induction and Maintenance Therapy** in Subjects with Moderately to Severely Active **Ulcerative Colitis**

PI: Bo Shen, MD
IRB: AAAV1713
Disease: **Ulcerative Colitis**
Treatment: **Lutikizumab** compared to **Adalimumab (Humira®)**

The purpose of this study is to see if the study drug Lutikizumab is safe and effective when compared to Adalimumab ((Humira®) at treating your moderate to severe ulcerative colitis.

Lutikizumab (ABT-981) is an investigational drug, not approved by United States Food and Drug Administration (U.S. FDA) for the treatment of ulcerative colitis. Lutikizumab is an immunoglobulin that blocks two proteins in the body, IL-1α and IL1β, which cause inflammation and are believed to play a role in UC. Adalimumab was first approved for the treatment of moderate to severe ulcerative colitis in 2012. No subject will only receive placebo. Placebo (non active drug) is only used in this study to maintain the blind so all subjects receive the same number of injections.

The study comprises of a 35-day Screening Period, a 12-week double-blind Induction Period, a 40-week double blind Maintenance Period and a 10-week safety Follow-Up Period after the last dose of study drug administration). At the beginning of the study, you will be randomly assigned (like a flip of a coin) into one of three groups: two groups will receive one of two different doses of lutikizumab and one group will receive adalimumab.

You will be one of approximately 5 subjects at Columbia University Irving Medical Center/New York Presbyterian Hospital (CUIMC/NYPH) and 200 subjects globally. Your study participation will be approximately 52 weeks.

Eligibility:

1. Age ≥ 18
2. Moderately to severely active Ulcerative Colitis, who have demonstrated inadequate response to, loss of response to, or intolerance to at least one of the following: oral aminosalicylates, corticosteroids and/or immunosuppressants, and/or advanced therapies). *Note: Subjects must not have previously received adalimumab (Humira) but may have received other advanced therapies (including other antiTNFs)

AMETRINE (GA45329): A Phase III, Multicenter, Double-Blind, Placebo-Controlled, Treat-Through Study To Assess The Efficacy And Safety Of Induction And Maintenance Therapy With **Ro7790121 In Patients With Moderately To Severely Active Ulcerative Colitis**

PI: Bo Shen, MD
IRB: AAAV3229
Disease: **Ulcerative Colitis**
Treatment: **Ro7790121 or Placebo**

The purpose of this study is to compare the effects, good or bad, of RO7790121 versus placebo in patients with ulcerative colitis. In this study, you will get either RO7790121 or placebo. You will have the opportunity to participate in an open-label extension phase (getting the active drug - RO7790121), if your condition has not improved.

RO7790121 is an investigational drug, not approved by United States Food and Drug Administration (U.S. FDA) for the treatment of ulcerative colitis. RO7790121 is an antibody directed against a protein called TL1A. TL1A is a protein found naturally in the body that has a role in inflammation. It has been found that TL1A levels and activity are increased in patients with ulcerative colitis. This increase is thought to lead to the development and worsening of the disease. Earlier research has shown that patients with ulcerative colitis have benefited from treatment with RO7790121.

The study will enroll up to 400 participants across global investigational sites. Your participation in this study will be approximately 70 weeks, depending on how your ulcerative colitis responds to the study drug.

Eligibility:

1.Age ≥ 18 to ≤ 80 years

2. Moderately to severely active Ulcerative Colitis, who have failed:
   a) prior conventional therapy (aminosalicylates, corticosteroids and/or immunosuppressants),

OR

   b) prior advanced therapy, which includes biologics or targeted small molecules, e.g., anti-TNF, anti-IL12/23, anti-integrin, S1P receptor modulators, JAK inhibitors, etc.

VICTRIVA (VedolIzumab Combination Therapy for the tReatment of patIents with actiVe Crohn's diseAse): A Randomized, Double-blind, Placebo-Controlled Phase 3b Study to Evaluate the Short and Long-term Efficacy and Safety of Dual Targeted Therapy With **Intravenous Vedolizumab and Oral Upadacitinib Compared With Intravenous Vedolizumab Monotherapy** for the Treatment of Adult Participants With Moderately to Severely Active Crohn's Disease

PI: Bo Shen, MD
IRB: AAAV2452
Disease: **Crohn's Disease**
Treatment: **Vedolizumab** (ENTYVIO) IV and **Upadacitinib** (RINVOQ) oral, versus **Vedolizumab** (ENTYVIO) IV alone

The purpose of this study is to compare the Efficacy and Safety of Vedolizumab with and Without Upadacitinib in Adults with Moderately to Severely Active Crohn's Disease.

The Takeda study drug used in this study is vedolizumab, a monoclonal antibody. Monoclonal antibodies are proteins made in laboratories that act like proteins in our bodies called antibodies. Vedolizumab acts specifically in the gut and works by preventing certain immune cells from going to the gut and helps reduce inflammation that can cause the symptoms (frequent bowel movements, and bleeding from the rectum) of CD. Vedolizumab will be given through IV, lasting approximately 30 minutes.

The other drugs used in this study are upadacitinib and/or upadacitinib placebo. Upadacitinib works by blocking the action of enzymes called Janus kinases (JAK), which help control inflammation by reducing the activity of the immune system. Upadacitinib and the upadacitinib placebo are in capsule form and are oral medications.

Both vedolizumab (Entyvio) and upadacitinib (Rinvoq) are medications that have been approved separately for treatment of patients with moderately to severely active CD who have had an inadequate response, lost response, or were intolerant to other treatments. However, in this study these two medications will be combined and this combination, called dual targeted therapy, is investigational.

The study will enroll up to 396 participants at up to 120 sites in regions including North and South America, Europe, Middle East and Asia. Biologic-naïve participants will not be recruited from the United States.

The study consists of 4 parts:

- Screening (Day 0); Induction (Week 0 -12)
- Maintenance (Week 13-52); Follow-Up (Week 53- 70)

Eligibility:

1. Age ≥ 18 to ≤ 65 years
2. Moderately to severely active CD, who have not previously experienced failure of treatment with vedolizumab or upadacitinib