Gastro One
Excellence in Digestive Health

Enrolling Research Studies
23 October 2018

- **Crohn's Disease Humira (AbbVie)**
- **Crohn's Disease (Eli Lilly)**
- **Ulcerative Colitis (Genentech)**
- **Crohn's Disease (Genentech)**
- **Crohn's Disease / Ulcerative Colitis (Gilead)**
- **Crohn's Disease (Takeda)**
- **Ulcerative Colitis (Pfizer)**
- **Ulcerative Colitis (Receptos)**
- **Ulcerative Colitis (Abbvie)**
- **Fistualizing Perianal Crohn's Disease (Gilead)**
- **Small Bowel Crohn's Disease (Gilead)**
- **Iron Deficiency Anemia (Shield)**
- **Crohn's Disease (Abbvie)**
- **NASH (Intercept)**
- **NASH Cirrhosis (Intercept)**
- **NASH Cirrhosis (Connatus)**
- **NAFLD (Gilead)**
- **NASH and NASH/Cirrhosis (Gilead)**
- **NASH (Proof of Concept no placebo) (Gilead)**
- **NASH (Allergan)**
- **NASH (Cirius)**
- **Gastroparesis (Allergan)**
- **Eosinophilic Esophagitis (SHIRE)**

Coming soon:

ABBVIE Crohn's

Looking for patients who would be a good Humira candidate (either anti-TNF naïve or secondary failure/intolerance to Remicade)

No need to have on Imuran.

No PLACEBO. Randomized to standard induction vs higher induction dose.

Call Amanda @ 2133

AbbVie Crohn's and UC

Upadacitinib (oral medication) for those who have inadequately responded to previous biologic treatment or conventional therapies.

Call Michelle @ 2107

GENENTECH UC

TNF Naïve

Very promising alpha 4-beta 7 and alpha E-beta 7 integrin.

Call Heather @ 2114

GENENTECH UC

Anti TNF Failures.

Very promising alpha 4-beta 7 and alpha E-beta 7 integrin.

Call Heather @ 2114

GENENTECH Crohn's Disease

Evaluate safety and efficacy of Etrolizumab as an induction and maintenance treatment for patients with Mod to Severely active Crohn's Disease

Call Heather @ 2114

GILEAD Crohn's and UC

- **Moderately to Severely Active Crohn's Disease / Ulcerative Colitis**
- **Filgotinib (JAK inhibitor)**

Call Keosha @ 2141

GILEAD Small Bowel Crohn's

- Mod to Severe active Crohn's disease.
- MRI based, no screening colonoscopy required

Call Keosha @ 2141

PFIZER Ulcerative Colitis

Moderate to severe UC

Placebo Controlled

Induction and chronic therapy using PF-06651600 and PF-06700841

Call Alisha @ 2116

GILEAD Fistulizing Crohn's DiseaseUlcerative Colitis

1-3 perianal fistulae with external openings of ≥ 4 weeks to evaluate the safety and efficacy of filtgotinib (oral medication)

Call Keosha @ 2141

ABBVIE Ulcerative Colitis

ABT-494 Induction and maintenance therapy in patient with mod to severely active UC. Must have failed corticosteroids, immunosuppressants and/or biologics

Call Michelle @ 2107

GILEAD Perianal Fistualizing Crohn's Disease

1-3 draining perianal fistula with external openings of ≥ 4 weeks

Evaluating the safety and efficacy of Filgotinib (placebo controlled)

Call Stephanie @ 2134

GILEAD Small Bowel Crohn's Disease

Placebo Controlled-MRI based.
No colonoscopy required.

Efficacy and safety study of Filgotinib

Call Stephanie @ 2134

SHIRE Ulcerative Colitis/ CD

Placebo controlled study of SHP647 (anti-MADCAM) in subjects with moderate to severe CD/ UC. Allows for mesalamine failures only

Call Beth @ 2128

GILEAD UC

Double blind study for Males

Monitor testicular safety of subjects on filgotinib with moderate to severe UC (ages 25-55)

CALL ALISHA @ 2116

ABBVIE Crohn's Disease

Induction study to assess the efficacy and safety of Risankizumab in subjects with Moderately to severely active Crohn's disease.

2 separate studies- 1 for Biologic failure and 1 for inadequate response

CALL MICHELLE @ 2107

SHIRE Ulcerative Colitis

Placebo controlled study with SHP647 (anti-MADCAM) in moderate to severe UC.

Allows mesalamine failures only.

Call Beth@ 2128

GENENTECH Ulcerative Colitis

Study to evaluate the efficacy of UTTR1147A compared with placebo and vedolizumab in patients with moderate to severe UC

Call Alisha @2116

INTERCEPT NASH

Long term study, placebo controlled, evaluating the safety and efficacy of Obeticholic acid in subjects with NASH.

Call Beth@ 2128

INTERCEPT NASH Cirrhosis

Placebo controlled use of Obeticholic acid in subjects with NASH compensated cirrhosis. Allows patients with burnt-out NASH.

Call Beth @ 2128

CYMABAY NASH

Placebo controlled NASH study to observe the effects of Seladelpar in patients with F1-F3 fibrosis.

Call Heather @ 2114

GILEAD NASH

For patients with F3-F4 NASH and elevated triglycerides.

Call Michelle@ 2107

ALLERGAN NASH

Cenicriviroc for subjects with NASH. F2-F3 only.

Requires liver biopsy at screening (if not done in the previous 180 days and repeat biopsy after treatment)

CALL GINA @ 2141

NGM NASH

Placebo Controlled NASH study for patients with F1-F3. Accepts historical biopsies if completed within 6 months and requires repeat biopsy.

Call Heather @ 2114

BMS NASH

Evaluating BMS-986036 in adults with F3-F4, requires weekly injections.

Call Alisha @ 2116

Novartis NASH

Study the safety and efficacy of a combination treatment of tropifexor and cenicriviroc in patients with NASH

Call Laurie @ 2128

CYMABAY PBC

52 week study to evaluate seladelpar in subjects with PBC and an inadequate response or intolerance to ursodeoxycholic acid. Requires alk phos >180.

Call Keosha @ 2141

SHIRE Eosinophilic Esophagitis

Double Blind placebo controlled study to evaluate Oral Budesonide suspension in adults with EOE.

CALL MICHELLE @ 2107