M16-067 (AbbVie)
Risankizumab (IL-23)
IP administration: IV and Subcutaneous injection
PI: Le-Chu Su, MD
Disease: ***moderate/severe Ulcerative Colitis***
Inclusion criteria: endoscopically and clinically confirmed moderate/severely active UC.
Intolerance or inadequate response to:
- aminosalicylates s (e.g., mesalamine, sulfasalazine, olsalazine, balsalazide
- oral locally acting steroids s (e.g., budesonide, beclomethasone)
- systemic steroids (prednisone or equivalent)
- immunomodulators (AZA; 6-MP; MTX), and/or
- biologic therapies (infliximab; adalimumab; golimumab; vedolizumab) and tofacitinib for UC
Exclusion criteria: - Prior exposure to p40 inhibitors (e.g., **ustekinumab [Stelara])** or p19 inhibitors (e.g., **risankizumab**). Approved **biologic** agent (e.g., infliximab, adalimumab, golimumab, vedolizumab) **within 8 weeks** prior to Baseline.

ADMIRE CD-II (Tigenix)
Cx601 (adult allogenic expanded adipose derived **Stem Cells)**
IP administration: injection under anesthesia
PI: Le-Chu Su, MD
Disease: ***Complex Fistula(s) due to Crohn's Disease***
Inclusion criteria: Nonactive to Mild CD with Complex Perianal Fistulas
Inadequate response, loss of response or intolerance while receiving **immunosuppressive agent (IS)** with azathioprine, 6-mercaptopurine or methotrexate; or **Biologics: TNFa antagonist** (Infliximab, Adalimumab, Certolizumab) or **Anti-integrin** (vedolizumab), or **Anti-IL-12/23** (ustekinumab).
Exclusion Criteria: actively draining Simple subcutaneous fistula; large ulcers (> 0.5 cm) in the rectum; **naïve** to medical treatment

M20-259 (AbbVie)
Risankizumab vs Ustekinumab (Stelara)
IP administration: IV and Subcutaneous injection
PI: Le-Chu Su, MD
Disease: ***moderate/severe Crohn's Disease***
Inclusion criteria: diagnosis of CD for at least 3 months; **inadequate** response to **anti-TNF** therapies: infliximab, adalimumab, certolizumab pegol or biosimilar
Exclusion criteria: Patients who **discontinued or had intolerance** to anti-TNF;
Received **biologics**: natalizumab and/or vedolizumab; risankizumab and ustekinumab (Stelara); Infliximab, certolizumab pegol and/or adalimumab including biosimilars within 8 weeks;

IM011023 (Bristol Meyer Squibb)
BMS-986165 (Tyrosine Kinase 2 inhibitor)
IP administration: Oral
PI: Bo Shen, MD
Disease: ***moderate/ severe Crohn's Disease***
Inclusion criteria: 18-75 yo; endoscopically and clinically active CD;
Inadequate response, loss of response (LOR), or intolerance to:
Oral 5-ASAs, Oral Corticosteroids, IV Corticosteroids, Immunomodulators, or Biologics (eg, infliximab, adalimumab, certolizumab pegol, natalizumab or vedolizumab); perianal fistulizing disease eligible; Patients can be included if treatment with a biologic was **stopped due to primary or secondary nonresponse**.
Exclusion criteria: **Inadequate response or LOR** to: Stelara, briakinumab, guselkumab, risankizumab, tildrakizumab, brazikumab and mirikizumab. Patient **have not had a treatment failure** (eg, an infusion reaction) may be eligible for inclusion.

TAK-018 (Takeda)
TAK-018
IP administration: Oral
PI: Bo Shen, MD
Disease: ***Prevention of postoperative Crohn's Disease recurrence***
Inclusion criteria: planned laproscopic ileocecal resection with primary anastomosis; **postop discontinuation of all medication for CD** treatment (including antibiotics).
Exclusion criteria: More than 3 previous CD surgical procedures; small bowel resection that exceeds 100 cm