UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

# The Inflammatory Bowel Disease Program

at University of Michigan Health is currently enrolling patients in the following clinical trials:

## M20-371 – ABBV-154 – CD

Phase 2 double-blind, placebo-controlled study of ABBV-154 for moderately to severely active CD patients

- Drug is an antibody-drug conjugate of adalimumab and a glucocorticoid receptor
- 4:1 Drug: Placebo
- 12-week induction, 40-week maintenance
- Can be on steroids
- Washouts 8-12 weeks
- **This study WILL enroll patients with history of certain cancers if 5+ years have elapsed**
- Key exclusions
  - ≥3 bowel resections
  - BMI under 18 or over 40
  - Intolerance to Humira
- Key inclusions
  - Must have failed a biologic
  - Must be 18-75 years old

## AMG592 – Efavaleukin Alfa – UC

Phase 2 double-blind, placebo controlled, for moderate to severely active UC patients

- **There are no drug exclusions for this study** (there are washout periods as stated above).
- 3:1 Drug: Placebo
- Study up to 52 weeks
- Can be on steroids
- Washouts 4-8 weeks
- Key exclusions
  - Disease limited to the rectum
  - Previous bowel resections
  - History of suicidal ideation
  - Active infections
- Inclusions
  - Must be between 18-80 years of age
  - Must have diagnosis of UC established for at least 3 months prior to enrollment.

## Stelara Food Study – CD patients, planning to start Stelara

This is a pilot study to determine whether a low serine vs high serine diet will reduce inflammation and improve response to Stelara.

- Subjects are provided 2 weeks' worth of meals and snacks, starting 1 week before the 1st dose of Stelara
- Will provide a scope to assess before starting Stelara, paid by insurance, and a 2nd scope in 25 weeks
- Must be willing to eat only the food provided (diet is vegetarian)
- Key inclusions:
  - SES-CD 7+, or 4+ if isolated ileal disease
  - Scheduled to begin Stelara in next 7-60 days
- Key exclusions:
  - CD complications like short bowel, toxic megacolon, ostomy
  - Diabetes
  - Soy allergy
  - Prior Stelara

**Contact the IBD Clinical Trial team at higginsscteam@umich.edu or call 734-615-4843.**