# **IBD** News

Fall 2012

U-M Division of Gastroenterology

# <u>NEW</u> IBD Videos Available on Website

o help you and your family better understand Crohn's disease and ulcerative colitis, the University of Michigan Crohn's and Colitis Program has created a number of short, educational videos called IBD School Series.

Our goals are for you to understand your disease, understand your choices of tests and treatments, and make more informed decisions that will improve your health and well being.

### www.med.umich.edu/IBD



Overview 101: Introduction 102: What is Crohn's? 103: What is colitis? 104: What causes IBD? 105: Can this affect my other organs? 106: Do I need surgery? 107: Do I need meds? 108: Will I live a normal life? 109: IBD mythbusters! 110: Where is my IBD?

### IBD Program Welcomes Dr. Beth Manoogian

r. Beth Manoogian has joined the IBD team at the University of Michigan as of July 2012. Dr. Manoogian attended the University of Michigan as an undergraduate, in medical school, and did her training in internal medicine and gastroenterology here. She will be seeing patients on Tuesdays in Livonia, and Wednesdays at the main medical center campus in Ann Arbor. She grew up in Michigan and likes running and making desserts.





### University of Michigan Health System

IBD Specialists are available in Ann Arbor by day:

#### MONDAY:

Leslie Aldrich, MD Ryan Stidham, MD Ellen Zimmermann, MD Kristen Boardman, PA-C Christine Brozo, PA-C

#### **TUESDAY:**

John Del Valle, MD Peter Higgins, MD Grace Elta, MD Kristen Boardman, PA-C Christine Brozo, PA-C

#### WEDNESDAY:

Beth Manoogian, MD Kristen Boardman, PA-C

#### THURSDAY

Peter Higgins, MD Leslie Aldrich, MD Kristen Boardman, PA

**FRIDAY:** Mike Rice, MD Kristen Boardman, PA

#### **Outreach:**

IBD Specialists are also available off the main medical campus two days a week:

TUESDAY: Livonia - Beth Manoogian, MD

#### THURSDAY:

Brighton - Michael Rice, MD Canton/East Medical Center -Leslie Aldrich, MD Canton - Ryan Stidham, MD



University of Michigan Health System

> **TO SPEAK TO A NURSE:** 734-936-0501

## TO MAKE AN APPOINTMENT:

Call 888-229-7408 for the appointment line, and specify that you want an IBD Specialist.

#### **VISIT OUR WEBSITE:**

U-M Inflammatory Bowel Disease Program www.med.umich.edu/IBD

U-M Division of Gastroenterology www.med.umich.edu/gi

# IBD Clinical Studies

Title: FINCH (observational study) for Crohn's Disease

**Description:** This study looks to assess MRE as an alternative imaging method for the assessment of inflammatory status in patients with Crohn's disease. If it's determined that a patient is eligible to participate, they will visit the University of Michigan multiple times over the course of 4 weeks. They will undergo one colonoscopy within the first 2 weeks and two MREs over the course of the second 2 weeks. Additionally, our study team will monitor their physical condition by performing various tests, such as vital sign measurements, physical examinations, and blood draws. Reimbursement will be given for each visit completed.

#### Title: UNITI for Crohn's Disease

#### Drug: Ustekinumab (Stelara ®) – IV infusion and SC injection

**Description:** Ustekinumab is a fully humanized monoclonal antibody that blocks activity of IL 12/23. It is approved in psoriasis and psoriatic arthritis (brand name Stelara). Ustekinumab showed promising efficacy in Centocor's Phase 2 studies in Crohn's disease patients who had failed or were intolerant to conventional therapy. This is the next study of this series, which will evaluate the efficacy of IV induction regimens of ustekinumab in inducing clinical response in subjects with moderately to severely active Crohn's disease that have failed or are intolerant to one or more TNF antagonist therapies.

Appointments are screening, week 0 (drug administration via IV infusion over 1 hour), week 3, week 6 and then week 8. At the week 8 appointment, subjects have the option to enter into the maintenance study **(IMUNITI)** where they will be re-randomized and given study drug for up to 4 years, every 4 weeks, via subcutaneous injection.

#### Title: OCTAVE for UC

#### Drug: Tofacitinib (CP-690,550) - oral medication

**Description:** This is a Phase 3 study in subjects with moderately to severely active Ulcerative Colitis. This medication is a JAK inhibitor made by Pfizer, Inc. JAK inhibitors interrupt signaling downstream of a multiplicity of cytokines, rather than blocking one cytokine at a time, as is the case of anti-TNF or Interleukin-6 blockers. It is taken in pill form.

The study is 9-weeks long and involves a screening visit, week 0/baseline appointment, follow-up visits at week 2, week 4, week 8 to assess your response to the medication. At week 9, we will assess the subject's eligibility to continue in the program. Those who complete the treatment period and have demonstrated benefit will be eligible to enter a placebo-controlled maintenance study of 52 weeks (A3921096). Subjects who complete the treatment period but have not demonstrated benefit will be eligible to enter an open-label extension study (A3921139), meaning there is no placebo and you are guaranteed active drug for 3 years.

#### Title: CADHUM for Crohn's disease

**Description:** In this study, we are testing whether patients who are in remission on Humira can stop their medication and only be re-dosed only if their inflammatory markers begin to increase. This would involve following participants very closely, with stool testing every 3 months. If there is a rise in the inflammatory markers, we will treat these patients with doses of Humira before symptoms occur to see if we can prevent flares. The goal of this study is to see if you can treat patients with Humira *only when they need the medicine*. If the study shows that Humira can be used only when needed for Crohn's disease, everyone with Crohn's disease will benefit.