



THE UNIVERSITY OF CHICAGO IBD CENTER

UCHICAGO IBD Clinical Trials Update May 2017

CONTACT THE IBD CLINICAL TRIALS TEAM:

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Contact us **before** starting the next drug!
Contact us **before** scoping the patient!

Currently Enrolling Therapeutic Trials— ACTIVE DISEASE ONLY:

CROHN'S DISEASE

RHB 104 (anti-microbial therapy)

- Oral: clarithromycin, rifabutin, & clofazamine vs. placebo
- Current treatment with 5-ASA, corticosteroids, immunomodulators or infliximab or adalimumab with active symptoms

CROHN'S OR ULCERATIVE COLITIS

Adalimumab: high vs. standard dose induction

- Subcutaneous; high dose induction vs. standard dose
- Prior biologics not allowed except infliximab
- Current other stable IBD therapies allowed
- Concurrent or prior treatment with a full and adequate course of corticosteroids or immunomodulators

CROHN'S OR ULCERATIVE COLITIS

Etrolizumab (anti- $\alpha 4\beta 7 / \alpha E\beta 7$ integrin antibody)

- Subcutaneous; placebo-controlled
- Off anti-TNF at least 8 weeks
- Prior vedolizumab or natalizumab not allowed
- **Crohn's**: failed/intolerant to corticosteroids, immunomodulators, or anti-TNF therapies within 5 years from screening
- **UC**: anti-TNF failure

CROHN'S DISEASE

Vedolizumab

- IV, Subcutaneous; placebo-controlled
- Failed or intolerant to 1 of the following agents: immunomodulators, anti TNF therapies, or corticosteroids
- Off biologics 5+ half lives

CROHN'S DISEASE

MEDI-2070 (fully human monoclonal antibody/ inhibits IL-23)

- IV and subcutaneous, placebo-controlled
- Failed or intolerant to at least one anti-TNF
- Current other stable IBD therapies allowed
- Off Anti-TNFs and Vedolizumab for 5 half-lives

CROHN'S DISEASE

Mongersen /GED-0301 (anti- Smad7 therapy)

- Oral; placebo-controlled
- Failed/intolerant to aminosaliclates; budesonide; systemic corticosteroids; immunosuppressants or biologics
- Biologic naïve

ULCERATIVE COLITIS

Etrolizumab vs. Adalimumab vs. Placebo

- Subcutaneous; anti- $\alpha 4\beta 7 / \alpha E\beta 7$ integrin vs. anti-TNF
- Biologic naïve
- Failed or intolerant to prior immunosuppressant treatments

ULCERATIVE COLITIS

RPC1063 (oral S1P receptor modulator)

- Oral; placebo-controlled
- Current treatment with oral aminosaliclates, prednisone, or budesonide
- Off biologics 5+ half lives

ULCERATIVE COLITIS

LY3074828 (humanized monoclonal antibody/ inhibits IL-23)

- IV and Subcutaneous; placebo-controlled
- Biologic naïve/failed/intolerant to one or more biologics
- Off anti-TNF 8+ weeks/off vedolizumab 12+ weeks

ULCERATIVE COLITIS

Lycera/ LYC-30937-EC (allosteric modulator targeting the mitochondrial ATP synthase, the F1F0-ATPase)

- Oral; placebo-controlled
- Currently receiving oral aminosaliclates or prednisone
- Off biologics for 12 weeks

For more details and to learn about other studies, please visit:
ibdclinicaltrials.uchicago.edu



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Digestive Diseases Center