UK Division of Digestive Diseases and Nutrition

Research News

October 21, 2024

Current Research

1) Fuzion:
Open to Enrollment
Coordinators—Sarah Turner/Minela Suljicic
PI—Deborah Flomenhoft, MD

A Phase 3, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab in Participants with Fistulizing, Perianal Crohn's Disease. Subjects must:

- Have at least one active draining perianal fistula
- Be naïve to biologics, a primary non-responder, secondary non-responder or intolerant to a maximum of 2 classes of biologic agents OR failure to respond to, or tolerate, oral corticosteroids or immunomodulators

Patients will be excluded if:

- They have prior exposure to IL-12/23 or IL-23 agents, with the exception of those who have had limited exposure to ustekinumab at its approved labeled dosage AND have met the required 16-week washout criterion AND have not demonstrated failure or intolerance to ustekinumab
- They have a history of or concurrent rectovaginal fistulas, rectal and/or anal stenosis (unless the participant undergoes surgical dilation prior to baseline), diverting stomas with anastomotic leakage, abscess or collections which are not properly drained
- They have current complications of Crohn's disease, such as symptomatic strictures or stenoses, short gut syndrome, or any other manifestation, that might be anticipated to require surgery, could preclude any fistula evaluation (both clinical and radiological) to assess response to therapy, or would possibly confound the ability to assess the effect of treatment with guselkumab

2) Nativ3:
Open to Enrollment
Coordinators—Sarah Turner/Minela Suljicic
PI—Alla Grigorian, MD

A randomised, double-blind, placebo-controlled, multicentre, Phase 3 study evaluating efficacy and safety of lanifibranor followed by an active treatment extension in adult patients with non-cirrhotic non-alcoholic steatohepatitis (NASH) and fibrosis 2 (F2)/fibrosis 3 (F3) stage of liver fibrosis. Subjects must:

- Have the following upon central biopsy reading process (can use local biopsy if done in last 7 months): diagnosis of NASH according to the Steatosis-Activity-Fibrosis (SAF): a) Steatosis score ≥1 b) Activity score: A3 or A4 c) Fibrosis score: F2 or F3
- Be on a stable dose of medications: GLP1 and statins for 3 months and anti-obesity treatments and vitamin E (if ≥ 400 IU/day) for 6 months prior to the qualifying liver biopsy (and dose must remain stable from time of biopsy until baseline). This list is not exhaustive
- Have no more than 5% weight change for 6 months prior to Screening and between liver biopsy and Baseline

Patients will be excluded if:

- They have documented causes of chronic liver disease other than NASH
- They have an AST <0.60xULN

Current Research—Closed to Enrollment

***1*) Duet CD:**
Closed to Enrollment
Coordinators—Sarah Turner/Minela Suljicic
PI—Deborah Flomenhoft, MD

A Phase 2b Randomized, Double-blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Crohn's Disease

If you have a patient who may qualify or be interested in one of our ongoing studies, please contact us:

Sarah — 859-323-6423 or skmatt0@uky.edu

Minela — 859-323-1086 or msu270@uky.edu

Did You Know...

We have several upcoming Crohn's Disease trials that will begin enrolling in soon.
Stay tuned or contact us for more details!