Featured data at DDW 2025

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Digestive Disease Week

San Diego, California
May 3-6, 2025

Johnson & Johnson Sponsored Studies

Poster or Session	Title	Presentation time (PST)
ASTRO Study		
Podium Presentation		
4241895	Efficacy and safety of subcutaneous guselkumab induction therapy in patients with moderately to severely active ulcerative colitis: Results through week 24 from the phase 3 ASTRO study	Monday, May 5 (3:16 –3:30pm)
QUASAR Studies		
Poster Presentations		
4241842	Efficacy and safety of guselkumab for ulcerative colitis through week 92 during the QUASAR long-term extension study	Sunday, May 4 (12:30 – 1:30pm)
4250438	Ulcerative Colitis-Related Medical Encounters in Patients Treated with Guselkumab: An analysis of the QUASAR Phase 3 Induction Study	Monday, May 5 (12:30 – 1:30pm)
4243181	Guselkumab induction therapy results in molecular resolution of inflammation in moderately to severely active ulcerative colitis: results from the Phase 3 QUASAR induction study	Sunday, May 4 (12:30 – 1:30pm)
4243186	Guselkumab maintenance therapy mediates further improvements in intestinal immune homeostasis and mucosal healing in patients with ulcerative colitis	Sunday, May 4 (12:30 – 1:30pm)
GRAVITI Studies		
Poster Presentation		
4238177	Efficacy of subcutaneous guselkumab induction therapy by baseline demographics and concomitant medications in participants with moderately to severely active Crohn's disease: Results from the phase 3 GRAVITI study	Sunday, May 4 (12:30 – 1:30pm)
Podium Presentation		
4235910	Corticosteroid sparing effects of treatment with guselkumab in patients with moderately to severely active Crohn's disease: Phase 3 GRAVITI study results through week 48	Monday, May 5 (5:00 – 5:15pm)
GALAXI/GRAVITI Study		
Poster Presentation		
4253526	Endoscopic patient clustering to investigate differential treatment effects of guselkumab and ustekinumab in Crohn's disease: post-hoc analysis of GALAXI and GRAVITI trials	Sunday, May 4 (12:30 – 1:30pm)

*Encore abstract

GALAXI Studies		
Poster Presentation		
4253931	Characterization of serum inflammatory proteins in response to guselkumab or ustekinumab induction and maintenance dosing in moderately to severely active Crohn's disease: Analysis of the GALAXI 2 and 3 Phase 3 studies	Sunday, May 4 (12:30 – 1:30pm)
4238114	Early disease efficacy of guselkumab therapy in biologic-naïve patients with moderately to severely active Crohn's disease: Post-hoc analysis from the phase 3 GALAXI 2 & 3 studies	Sunday, May 4 (12:30 – 1:30pm)
4236013	Corticosteroid sparing effects of treatment with guselkumab in patients with moderate to severely active Crohn's disease: Phase 3 GALAXI 2/3 results through week 48	Sunday, May 4 (12:30 – 1:30pm)

GRAVITI/GALAXI Studies		
Poster Presentation		
4236339	Efficacy of guselkumab intravenous and subcutaneous induction: Symptoms, heath-related quality of life, and inflammatory biomarker results from the GALAXI and GRAVITI studies	Sunday, May 4 (12:30 – 1:30pm)
4237148	Comparison of pharmacodynamic and mechanistic response of guselkumab subcutaneous and intravenous induction in moderately to severely active Crohn's disease: molecular analysis of the GRAVITI and GALAXI Phase 3 studies	Sunday, May 4 (12:30 – 1:30pm)

IBD Pooled Study		
Poster Presentation		
4243278	Safety of guselkumab in inflammatory bowel disease up to 1 year: Integrated safety analysis of Phase 2 and 3 studies in Crohn's disease and ulcerative colitis	Sunday, May 4 (12:30 – 1:30pm)

PURSUIT Study		
Poster Presentations		
4247579	Efficacy and safety of golimumab in pediatric patients with moderately-to-severely active ulcerative colitis: results from the Phase 3 open-label PURSUIT 2 study	Sunday, May 4 (12:30 – 1:30pm)

UNITI Jr. Study		
Podium Presentations		
4243327	Ustekinumab open-label induction and randomized blinded maintenance therapy in pediatric participants with moderately to severely active Crohn's disease: the Phase 3 UNITI Jr study	Saturday, May 3 (12:30 – 1:30pm)

*Encore abstract

Real World Evidence Studies

Poster or Session	Title	Presentation time (PST)
OPTUM Study		
Poster Presentations		
4230728	Treatment discontinuation in patients with ulcerative colitis or Crohn's disease receiving biologic therapies that require intravenous infusions during induction and subcutaneous injections during maintenance	Tuesday, May 6 (12:30 – 1:30pm)
Mt. Sinai Canada Chart Review Study		
Poster Presentation		
4252285	The impact of disease status after biologic induction therapy on long-term outcomes in persons with Crohn's disease	Tuesday, May 6 (12:30 – 1:30pm)
IBDifficult Study		
Poster Presentation		
4253188	Comorbidities and extraintestinal manifestations among patients with difficult-to-treat inflammatory bowel disease in Latin America	Sunday, May 4 (12:30 – 1:30pm)

Collaborative Studies & Investigator Initiated Studies

Poster or Session	Title	Presentation time (PST)
Mt Sinai Wearable Devices Study		
Poster Presentations		
4254070	Longitudinally collected physiological data from wearable devices identifies inflammatory activity following biologic initiation	Sunday, May 4 (12:30 – 1:30pm)
MOSAIK Study		
Poster Presentation		
4260589	Five-year clinical outcomes and disease course of newly-diagnosed moderate-to-severe ulcerative colitis: a prospective nationwide multicenter MOSAIK cohort study in Korea	Saturday, May 3 (12:30 – 1:30pm)

*Encore abstract

CD-FIB Study		
Poster Presentation		
4259087	PRO-C6 as a biomarker for fibrosis in Crohn's disease: differentiation, correlation, and limitations	Saturday, May 3 (12:30 – 1:30pm)

Trajectories Meta-analysis Study		
Poster Presentation		
4244085	Symptom response trajectory analysis identifies distinct subpopulations in moderate-to-severe ulcerative Colitis linked to maintenance outcomes: a patient level Post-hoc analysis of 2,378 participants across 6 rct's with 8 advanced therapies	Sunday, May 4 (12:30 – 1:30pm)

PathAI Collaboration Study		
Poster Presentation		
4247949	Consortium-driven development of pathology foundation model-based approaches for automated scoring of histopathology in ulcerative colitis	Sunday, May 4 (12:30 – 1:30pm)

TREMFYA® IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA®?

TREMFYA® is a prescription medicine that may cause serious side effects, including:

- **Serious Allergic Reactions.** Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - swelling of your face, eyelids, lips, mouth, tongue or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching

- **Infections.** TREMFYA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

- fever, sweats, or chills
- muscle aches
- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

- **Liver problems**. With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA®. Your healthcare provider may stop treatment with TREMFYA® if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:
  - unexplained rash
  - vomiting
  - tiredness (fatigue)
  - yellowing of the skin or the whites of your eyes o nausea
  - stomach pain (abdominal)
  - loss of appetite
  - dark urine

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Do not use TREMFYA® if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

Before using TREMFYA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about TREMFYA®?"
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.

  Pregnancy Registry: If you become pregnant during treatment with TREMFYA®, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA®. You can enroll by visiting www.mothertobaby.org/ongoing-study/tremfya-guselkumab, by calling 1-877-311-8972, or emailing MotherToBaby@health.ucsd.edu. The purpose of this registry is to collect information about the safety of TREMFYA® during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

What are the possible side effects of TREMFYA®?

TREMFYA® may cause serious side effects. See "What is the most important information I should know about TREMFYA®?"

The most common side effects of TREMFYA® include: respiratory tract infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, stomach pain, and bronchitis.

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

Please read the full Prescribing Information, including Medication Guide for TREMFYA®, and discuss any questions that you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Dosage Forms and Strengths: TREMFYA® is available as 100 mg/mL and 200 mg/2mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

STELARA® IMPORTANT SAFETY INFORMATION

STELARA® is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects including:

Serious Infections

STELARA® may lower your ability to fight infections and may increase your risk of infections. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.

Before starting STELARA®, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
  - fever, sweats, or chills
  - muscle aches
  - cough
  - shortness of breath
  - blood in phlegm
  - weight loss
  - warm, red, or painful skin or sores on your body
  - diarrhea or stomach pain
  - burning when you urinate or urinate more often than normal
  - feel very tired
- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. STELARA® can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take STELARA® may also be more likely to get these infections.

Cancers

STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA®. Tell your doctor if you have any new skin growths.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.

Serious Allergic Reactions

Serious allergic reactions can occur. Stop using STELARA® and get medical help right away if you have any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

Lung Inflammation
Cases of lung inflammation have happened in some people who receive STELARA® and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before receiving STELARA®, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections, cancers, or PRES.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your doctor if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine).

People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can cause serious problems. **You should not receive the BCG vaccine during the one year before receiving STELARA® or one year after you stop receiving STELARA®.**

- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your doctor should decide if you will receive STELARA®.
- received STELARA® while you were pregnant. It is important that you tell your baby's healthcare provider before any vaccinations are given to your baby.
- are breastfeeding or plan to breastfeed. STELARA® can pass into your breast milk.
- talk to your doctor about the best way to feed your baby if you receive STELARA®.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

When prescribed STELARA®:

- Use STELARA® exactly as your doctor tells you to.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that STELARA® be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain, and joint pain. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

Please click to read the full Prescribing Information and Medication Guide for STELARA® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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