# Featured data at ECCO 2025

Johnson&Johnson

## European Crohn's and Colitis Organisation Congress

Berlin, Germany
February 19-22, 2025

# Johnson & Johnson Sponsored Studies

| Poster or Session | Title | Presentation time and location (CET) |
|---|---|---|
| *ASTRO Study* | | |
| **Oral Presentation** | | |
| OP10 | Efficacy and safety of subcutaneous guselkumab induction therapy in patients with ulcerative colitis: Results through week 12 from the phase 3 ASTRO study | Friday, February 21 (10:15 –10:25) |
| *QUASAR Study* | | |
| **Poster Presentations** | | |
| P0061 | Guselkumab induction therapy results in molecular resolution of inflammation in moderately to severely active ulcerative colitis: results from the Phase 3 QUASAR induction study | Friday, February 21 (12:40 –13:40) |
| P1169 | Guselkumab maintenance treatment improves health-related quality of life in patients with moderately to severely active ulcerative colitis: Phase 3 QUASAR maintenance study | Friday, February 21 (12:40 – 13:40) |
| P1141 | Guselkumab efficacy and safety in East Asian participants with moderate to severely active ulcerative colitis: Subgroup analysis of the Phase 2b/3 QUASAR induction and maintenance studies | Friday, February 21 (12:40 – 13:40) |
| **Digital Oral Presentation** | | |
| DOP069 | Guselkumab maintenance therapy mediates further improvements in intestinal immune homeostasis and mucosal healing in patients with ulcerative colitis | Friday, February 21 (9:00 – 9:06) |
| *GRAVITI Study* | | |
| **Oral Presentation** | | |
| OP33 | Efficacy and safety of subcutaneous guselkumab induction therapy in patients with moderately to severely active Crohn's disease: Results through Week 48 from the phase 3 GRAVITI study | Saturday, February 22 (9:20 – 9:30) |
| **Poster Presentations** | | |
| P0843 | Efficacy by baseline disease characteristics of subcutaneous guselkumab induction therapy in patients with moderately to severely active Crohn's disease: Results at Week 12 from the phase 3 GRAVITI study | Friday, February 21 (12:40 – 13:40) |
| P0670 | 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 | Friday, February 21 (12:40 – 13:40) |



*Encore abstract

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| P0872 | 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 | Friday, February 21 (12:40 – 13:40) |
| P1149 | Guselkumab improves health-related quality of life as measured by PROMIS-29 in participants with moderately to severely active Crohn's disease: Phase 3 GRAVITI study | Friday, February 21 (12:40 – 13:40) |
| P1030 | Efficacy and safety of subcutaneous guselkumab in East Asian participants with moderately to severely active Crohn's disease: Subgroup analysis of the Phase 3 GRAVITI study | Friday, February 21 (12:40 – 13:40) |

| *GALAXI Study* | | |
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| Digital Oral Presentation | | |
| DOP060 | 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 | Friday, February 21 (8:30 – 9:30) |
| Poster Presentations | | |
| P0917 | 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 | Friday, February 21 (12:40-13:40) |
| P0891 | Efficacy and safety of subcutaneous guselkumab rescue therapy in patients with moderately to severely active Crohn's disease and inadequate response to ustekinumab: Phase 2 GALAXI 1 study long-term extension results | Friday, February 21 (12:40-13:40) |
| P0976 | Guselkumab efficacy and safety in East Asian participants with moderate to severely active Crohn's disease: Subgroup analysis of the GALAXI 2 & 3 Phase 3 studies | Friday, February 21 (12:40-13:40) |

| *GRAVITI/GALAXI Studies* | | |
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| Poster Presentations | | |
| P0197 | 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 | Friday, February 21 (12:40-13:40) |
| P0669 | Safety of intravenous and subcutaneous guselkumab induction administration: Results from the GALAXI and GRAVITI studies in participants with Crohn's Disease | Friday, February 21 (12:40-13:40) |



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| *IBD Pooled Study* | | |
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| Poster Presentation | | |
| P0608 | 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 | Friday, February 21 (12:40-13:40) |

| *UNIFI Jr/ UNITI Jr Studies* | | |
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| Poster Presentation | | |
| P1123 | Baseline characteristics and nutrition in patients with moderately to severely active inflammatory bowel disease: Results from the phase 3 UNITI Jr and UNIFI Jr trials | Friday, February 21 (12:40-13:40) |

## Market Access & Epidemiology

| Poster or Session | Title | Presentation time and location (CET) |
|---|---|---|
| *EPILATAM-IBD Study* | | |
| Poster Presentations | | |
| P1257 | Difficult-to-treat inflammatory bowel disease in Latin American countries: prevalence and clinical characteristics | Friday, February 21 (12:40-13:40) |
| P0278 | Healthcare resource utilization by patients with difficult-to-treat inflammatory bowel disease in Latin American countries | Friday, February 21 (12:40-13:40) |

| *Literature Review Study* | | |
|---|---|---|
| Poster Presentation | | |
| P1263 | Real-World Evidence Needs for Treatment Sequence Disease Modelling in Refractory Inflammatory Bowel Disease | Friday, February 21 (12:40-13:40) |

| *UNIFI/PURSUIT/ ACT-1/ACT-2 Studies* | | |
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| Poster Presentation | | |
| P0559 | Endoscopic healing at 1-year and association with long-term quality of life in ulcerative colitis: A pooled clinical trial analysis adjusting for 1-year clinical remission status | Friday, February 21 (12:40-13:40) |



*Encore abstract

# 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

**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.
- 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:** upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections 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 in a 100 mg/mL prefilled syringe and One-Press patient-controlled injector for subcutaneous injection, a 200 mg/2 mL prefilled syringe and prefilled pen (TREMFYA® PEN) for subcutaneous injection, and 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® if you are breastfeeding or plan to breastfeed. It is thought that STELARA® passes 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.**