

United European Gastroenterology Week

Berlin, Germany October 4-7, 2025

| J&J Sponsored Studies | | | |
|----------------------------------|--|-----------------------------|--|
| Presentation or Poster Number | Title | Presentation time (CEST) | |
| Icotrokinra† St | Icotrokinra [†] Study | | |
| ANTHEM Study | | | |
| Podium Presentation | | | |
| OP206 | Icotrokinra, a targeted oral peptide that selectively blocks il-23 receptor activation, in moderately to severely active ulcerative colitis: week 12 results | Tuesday, October 7 | |
| | from the phase 2b, randomized, double-blind, placebo-controlled, treat-through, dose-ranging ANTHEM-uc trial | 15:06 – 15:18 | |

| TREMFYA® (guselkumab) studies | | | |
|-------------------------------|--|-------------------------------------|--|
| ASTRO Study | ASTRO Study | | |
| | Podium Presentation | | |
| OP203 | Efficacy and safety of subcutaneous guselkumab induction and maintenance therapy in patients with ulcerative colitis: results through week 48 from the phase 3 ASTRO study | Tuesday, October 7 14:30 – 14:42 | |
| | Moderated Poster Presentation | | |
| MP724 | Effect of guselkumab subcutaneous induction and maintenance on symptoms of moderately to severely active ulcerative colitis as measured by the UC-PRO/SS: results from the phase 3 ASTRO study | Monday, October 6 8:48 – 8:54: | |
| ePoster | | | |
| PP0532 | Impact of subcutaneous guselkumab therapy on molecular inflammation in | Saturday, October 4 | |
| | patients with ulcerative colitis: results from phase 3 ASTRO study | 9:00 | |

| QUASAR Study | | | |
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| | Podium Presentation | | |
| OP205 | Maintenance of endoscopic and histologic improvements with guselkumab for ulcerative colitis at week 92 of the QUASAR long-term extension study | Tuesday, October 7 | |
| ePoster | | | |
| PP0492 | Efficacy of guselkumab in moderately to severely active ulcerative colitis by extent of disease and inflammatory burden: subgroup analysis of the phase 3 QUASAR maintenance study | Saturday, October 4 9:00 | |

| ASTRO-QUASAR Studies | | |
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| Moderated Poster Presentation | | |
| MP723 | Benefit-risk of guselkumab compared to placebo in the treatment of moderately to severely active ulcerative colitis | Tuesday, October 7 10:18 – 10:24 |

| GALAXI Study | | | |
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| | Podium Presentations | | |
| OP005 | Efficacy and safety of subcutaneous guselkumab rescue therapy in patients with moderately to severely active Crohn's disease and inadequate response to ustekinumab: results from GALAXI 1, 2, & 3 long-term extension | Sunday, October 5 16:06 – 16:18 | |
| OP039 | Molecular differentiation of guselkumab and ustekinumab in moderately to severely active Crohn's disease: post hoc analysis of the GALAXI 2 and 3 phase 3 studies | Sunday, October 5 17:48 – 18:00 | |
| Moderated Poster Presentation | | | |
| MP582 | Guselkumab maintenance dose regimens in patients with high disease activity and severity: subgroup analysis of participants with moderately to severely active Crohn's disease in the GALAXI phase 3 studies | Monday, October 6 16:12 – 16:18 | |

| GALAXI/GRAVITI Studies | | | |
|------------------------|--|------------------------------------|--|
| | ePoster | | |
| PP0548 | Comparison of pharmacodynamic serum IL-22 and the mechanistic tissue molecular changes between guselkumab subcutaneous and intravenous induction in moderately active crohn's disease: post-hoc analysis of the GRAVITI and GALAXI phase 3 studies | Sunday, October 4 9:00 | |
| | Moderated Poster Presentations | | |
| MP532* | Endoscopic patient clustering to investigate differential treatment effects of guselkumab and ustekinumab in crohn's disease: post-hoc analysis of GALAXI and GRAVITI trials | Monday, October 6 15:18 – 15:24 | |
| MP581 | Guselkumab pharmacokinetics and exposure-response relationships are consistent following intravenous versus subcutaneous induction in participants with Crohn's disease | Monday, October 6 16:00 – 17:00 | |
| MP586 | Efficacy by baseline disease characteristics of intravenous and subcutaneous guselkumab induction therapy in patients with moderately to severely active crohn's disease: results at week 12 from the phase 3 GALAXI and GRAVITI studies | Monday, October 6 16:36 – 16:42 | |

| GRAVITI Study | | |
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| Moderated Poster Presentation | | |
| MP306 | Effects of subcutaneous guselkumab induction and maintenance on histologic outcomes in patients with moderately to severely active crohn's disease in GRAVITI, a phase 3 double-blind, placebo-controlled, treat-through study | Monday, October 6 8:48 – 8:54 |

| CRD3003 Study | | |
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| Moderated Poster Presentation | | |
| MP583 | Efficacy of guselkumab for small bowel lesions using balloon assisted enteroscopy: a phase 3, open-label, multicenter study | Monday, October 6 16:18 – 16:24 |

| Market Access and Real-World Value and Evidence | | | |
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| Presentation or Poster Number | Title | Presentation times (CEST) | |
| | Poster Presentations | | |
| OP221 | Therapeutic and hospitalisation outcomes after first-line anti-TNF in inflammatory bowel disease: insights from the EPITHERA study using data from | Tuesday, October 7 | |
| | the French national health data | 15:06 – 15:18 | |
| | Moderated Poster Presentation | | |
| MP142 | Guselkumab versus risankizumab as maintenance treatment for moderately to severely active ulcerative colitis: Network meta-analyses of clinical remission and endoscopic outcomes | Sunday, October 5 | |
| | | 12:48 – 12:54 | |
| | ePosters | | |
| PP1117 | Earlier use of guselkumab is projected to yield long-term sustained remission in | Saturday, October 5 | |
| | patients with moderate-to-severe ulcerative colitis | 9:00 | |
| PP0500 | Comparative efficacy of guselkumab vs. risankizumab in induction phase for | Saturday, October 4 | |
| | Crohn's disease: an anchored MAIC analysis | 9:00 | |

TREMEYA® 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

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 <u>Prescribing Information</u>, including <u>Medication Guide</u> 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. Some people have serious infections during treatment with STELARA®, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

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

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

Before starting STELARA®, tell your healthcare provider 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 healthcare provider 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 healthcare provider 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 healthcare provider if you have any new skin growths.

Serious Allergic Reactions

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

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. Tell your healthcare provider right away if you get any symptoms of PRES during treatment with STELARA®, including: headache, seizures, confusion, and vision problems.

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 healthcare provider right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before you use or receive STELARA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections or cancers.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your healthcare provider 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 are being treated with STELARA® should avoid receiving live vaccines. Tell your healthcare provider 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 avoid receiving 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 healthcare provider should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. STELARA® can pass into your breast milk.
- talk to your healthcare provider about the best way to feed your baby if you receive STELARA®.

Tell your healthcare provider 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 healthcare provider and pharmacist when you get a new medicine.

When prescribed STELARA®:

- Use STELARA® exactly as your healthcare provider tells you to. The healthcare provider will determine the right dose of STELARA®, the amount for each injection, and how often it should be given. Be sure to keep all scheduled follow-up appointments.
- STELARA® is intended for use under the guidance and supervision of your healthcare provider. In children, it is recommended that STELARA® be administered by a healthcare provider. If your healthcare provider decides that you or a caregiver may give your injections of STELARA® at home, you or a caregiver should receive training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® until you have been shown how to inject STELARA® by a healthcare provider.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, influenza, 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 <u>Prescribing Information</u> and <u>Medication Guide</u> 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.