

American College of Gastroenterology

Phoenix, Arizona October 24-29, 2025

J&J Sponsored Studies			
Presentation or Poster Number	Title	Presentation time (MST)	
Icotrokinra Stud	Icotrokinra Studies		
ANTHEM Study	ANTHEM Study		
	Podium Presentation		
Presentation #65	Efficacy and safety of icotrokinra, a targeted oral peptide that selectively blocks IL-23 receptor activation, in ulcerative colitis: results from week 28 of ANTHEM-UC, a phase 2b dose-ranging trial	Wednesday, October 29 8:30am – 8:40am	

TREMFYA® (guselkumab) studies			
ASTRO Study	ASTRO Study		
	Podium Presentation		
Presentation #4*	Efficacy and safety of subcutaneous guselkumab induction and maintenance therapy in patients with ulcerative colitis: results through	Monday, October 27	
	week 48 from the phase 3 ASTRO study	8:36am – 8:48am	
	Posters		
P1150	Effect of guselkumab subcutaneous induction and maintenance on symptoms of moderately to severely active ulcerative colitis as	Sunday, October 26	
F 1130	measured by the UC-PRO/SS: results from the phase 3 ASTRO study	3:30pm – 7:00pm	
P1082*	Impact of subcutaneous guselkumab induction therapy on molecular inflammation in patients with ulcerative colitis: results from the phase 3	Sunday, October 26	
1 1002	ASTRO study	3:30pm – 7:00pm	

GALAXI Studies		
Podium Presentations		
Presentation #70*	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	Wednesday, October 29 9:20am – 9:30 am
Presentation #68*	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	Wednesday, October 29 9:00am – 9:10 am
	Poster	
P5445*	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	Tuesday, October 28 10:30am – 4:00pm

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GALAXI/GRAVITI Studies		
Posters		
P1066	Long-term efficacy and safety of guselkumab through week 96 after intravenous or subcutaneous induction in participants with Crohn's disease: findings from the long-term extension periods of the phase 3 GALAXI 2, GALAXI 3, and GRAVITI Studies	Sunday, October 26 3:30pm – 7:00pm
P1120*	Comparison of serum IL-22 and tissue molecular changes between guselkumab subcutaneous and intravenous induction in moderately to severely active Crohn's disease: post-hoc analysis of the GRAVITI and GALAXI studies	Sunday, October 26 3:30pm – 7:00pm
P3193*	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 27 10:30am – 4:00pm
P5433*	Guselkumab pharmacokinetics and exposure-response relationships are consistent following intravenous versus subcutaneous induction in participants with Crohn's disease	Tuesday, October 28 10:30am – 4:00pm

ASTRO/QUASAR Studies		
Poster		
P5307	Pharmacokinetics and exposure-response relationships of guselkumab intravenous or subcutaneous induction in participants with ulcerative colitis	Tuesday, October 28 10:30am – 4:00pm

QUASAR Study		
	Posters	
P1147*	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	Sunday, October 26 3:30pm – 7:00pm
P3189*	Maintenance of endoscopic and histologic improvements with guselkumab for ulcerative colitis at week 92 of the QUASAR long-term extension study	Monday, October 27 10:30am – 4:00pm

GRAVITI Study		
	Poster	
P3192*	Effects of subcutaneous guselkumab induction and maintenance on histologic outcomes in patients with moderately to severely active	Monday, October 27
P3192*	Crohn's disease in GRAVITI, a Phase 3 double-blind, placebo-controlled, treat-through study	10:30am – 4:00pm

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APEX Study		
	Poster	
P3167*	Inhibition of structural damage progression with guselkumab in participants with active psoriatic arthritis: results through week 24 of	Monday, October 27
1 0101	the phase 3b, randomized, double-blind, placebo-controlled APEX study	10:30am – 4:00pm

Market Access and Real-World Value and Evidence		
Presentation or Poster Number	Title	Presentation times (MST)
GALAXI and GR	AVITI Studies	
	Posters	
P3245	Longer sustained remission in Crohn's disease with guselkumab versus ustekinumab treatment: projections from a disease model	Monday, October 27 10:30am – 4:00pm
P3246*	Induction efficacy of subcutaneous guselkumab vs advanced therapies in moderately-to-severely active Crohn's disease: a Bayesian network meta-analysis	Monday, October 27 10:30am – 4:00pm

Claims Database Analysis Study			
	Posters		
P3338	Treatment discontinuation in patients with inflammatory bowel disease (IBD) receiving biologic therapies that require intravenous (IV) infusions	Monday, October 27	
	during induction and subcutaneous (SC) injections during maintenance: a claims-based study using data from two large US databases	10:30am – 4:00pm	
P5321	Investigating unmet needs among advanced therapy-naïve patients with	Tuesday, October 28	
	Crohn's disease treated with ustekinumab or risankizumab	10:30am – 4:00pm	
P5322	Investigating unmet needs among advanced therapy-naïve patients with	Tuesday, October 28	
	Crohn's disease treated with ustekinumab or upadacitinib	10:30am – 4:00pm	

Adelphi Study		
	Posters	
P3244	Symptom and quality of life benefits of achieving deep remission – a real-	Monday, October 27
1 0244	world study of patients with Crohn's disease	10:30am – 4:00pm
P3247	Symptom and quality of life benefits of achieving deep remission – a real-	Monday, October 27
	world study of patients with ulcerative colitis	10:30am – 4:00pm

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WHAT IS TREMFYA® (guselkumab)?

TREMFYA® is a prescription medicine used to treat adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).

TREMFYA® is a prescription medicine used to treat adults and children 6 years and older who also weigh at least 88 pounds (40 kg) with active psoriatic arthritis.

TREMFYA® is a prescription medicine used to treat adults with moderately to severely active ulcerative colitis.

TREMFYA® is a prescription medicine used to treat adults with moderately to severely active Crohn's disease.

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)
- o skin rash, hives
- o Itching
- swelling of your face, eyelids, lips, mouth, tongue or throat
- o trouble breathing or throat tightness
- o chest tightness
- 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:

o fever, sweats, or chills

o shortness of breath

o muscle aches

o blood in your phlegm (mucus)

o weight loss

o burning when you urinate or urinating more often than normal

- o cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- o diarrhea or stomach pain

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• 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®. With the treatment of plaque psoriasis or psoriatic arthritis, your healthcare provider may do blood tests to check your liver before and as necessary 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:

o unexplained rash

o stomach pain (abdominal)

o vomiting

o loss of appetite

o tiredness (fatigue)

o dark urine

- o yellowing of the skin or the whites of your eyes
- o nausea

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®. Children should be brought up to date with all vaccines before starting 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, bronchitis, feeling very tired (fatigue), fever (pyrexia), and skin rash (rash).

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 <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.

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



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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.

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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.