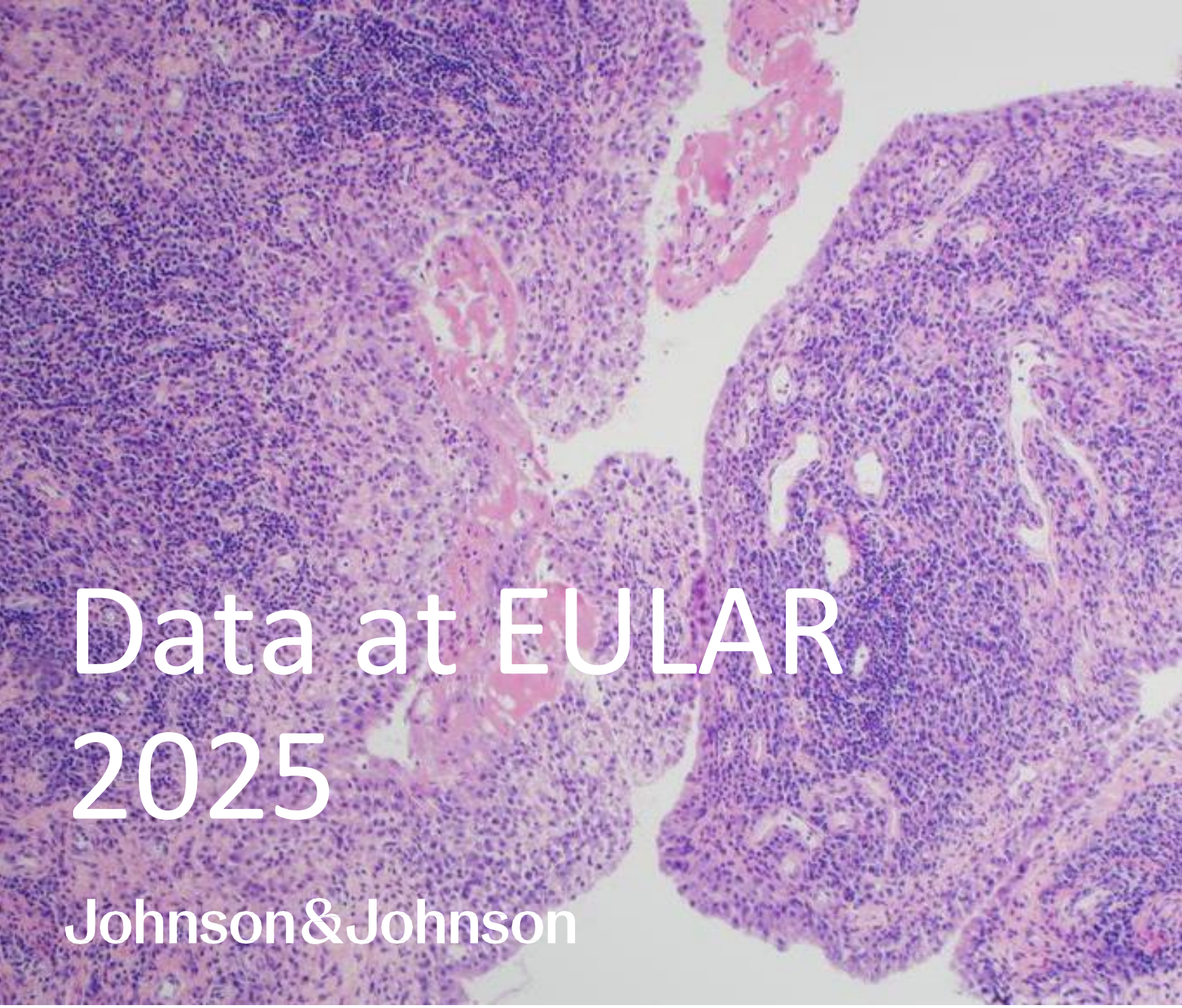

Data at EULAR 2025

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European Alliance of Associations for Rheumatology (EULAR) 2025

Barcelona, Spain
June 11 - 14, 2025

Johnson & Johnson sponsored TREMFYA® (guselkumab) studies

Abstract Number	Title	Presentation time (CEST)
Psoriatic arthritis		
APEX Study Abstract		
LB0010	Inhibition of Structural Damage Progression With the Selective IL-23i Guselkumab in Participants With Active PsA: Results Through Week 24 of the Phase 3, Randomized, Double-Blind, Placebo-Controlled APEX Study	Oral presentation Saturday, June 14 10:30-10:40
DISCOVER-1, DISCOVER-2, COSMOS Study Abstracts		
OP0094	Biological Sex-Related Differences in Radiographic Progression and Relationship with Early Clinical Response: Post Hoc Analysis of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study in Biologic-Naive Participants with Active Psoriatic Arthritis Treated with Guselkumab	Oral presentation Wednesday, June 11 17:20-17:30
POS1024 *	Impact of Prior Tumor Necrosis Factor Inhibitor Treatment and Baseline Psoriatic Arthritis Disease Activity on Minimal Clinically Important Improvement Thresholds for Efficacy Outcomes: Post Hoc Analysis of 3 Phase 3 Studies of Guselkumab in Patients With Active Psoriatic Arthritis	Friday, June 13 12:00-13:30
ABS0974	Early Improvements in Clinical Disease Activity Index for Psoriatic Arthritis and its Components With Guselkumab Predict Clinical Response in TNFi-Experienced and Biologic-Naïve Participants with Active Psoriatic Arthritis: Post Hoc	Abstract book only
ABS1069 *	Sex-Related Differences in Baseline Patient and Disease Characteristics: Post Hoc Analyses of Three Phase 3, Randomized, Double-Blind, Placebo-Controlled Studies in Patients With Active Psoriatic Arthritis	Abstract book only
ABS0993 *	Guselkumab Shows Similar Domain-Specific Efficacy in Females and Males With Active Psoriatic Arthritis: Post Hoc Analyses of Three Phase 3, Randomized, Double-Blind, Placebo-Controlled Studies	Abstract book only
Manhattan Study Abstract		
POS0611	One Year Persistence and Effectiveness of Guselkumab or TNFi as Second-Line Treatment After Receiving a TNFi as First-Line Therapy to Treat Active Psoriatic Arthritis: Manhattan Study	Wednesday, June 11 15:30-16:30
FINGUS Study Abstract		
ABS0249	Real-World Guselkumab Use in Finnish Patients with Psoriatic Arthritis: Adherence, Persistence, and Patient-Reported Outcomes	Abstract book only
TIGER Study Abstract		
POS0104	Whole-Body MRI (WB-MRI) to Assess Response to Adalimumab, Guselkumab, and Ustekinumab in Psoriatic Arthritis (PsA): Imaging Results From the TIGERS Study	Thursday, June 12 12:12-12:18

*Encore abstract

Health Plan Claims Database Study Abstracts		
ABS1075 *	On-Label Persistence Through 24 Months in Patients With Psoriatic Arthritis Using Guselkumab or Subcutaneous Interleukin-17A Inhibitors	Abstract book only
POS1025	On-label Persistence Through 24 Months Among Patients With Psoriatic Arthritis Initiating Guselkumab or Subcutaneous TNF Inhibitors	Friday, June 13 12:00-13:30
Psoriasis		
VISIBLE Study Abstract		
POS0816 *	VISIBLE: Guselkumab Impact on Psoriatic Arthritis at Week 16 in Participants With Moderate to Severe Psoriasis Across All Skin Tones	Thursday, June 12 12:00-13:30

Johnson & Johnson sponsored nipocalimab studies

Abstract Number	Title	Presentation time (CEST)
Sjogren's disease		
DAHLIAS Study Abstracts		
POS0462 *	Observed and Simulated Pharmacokinetics and Pharmacodynamics of Nipocalimab, a Fully Human FcRn-Blocking Monoclonal Antibody, in Adults With Sjögren's Disease: Results From a Phase 2, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study	Wednesday, June 11 15:30-16:30
POS0818 *	Pharmacodynamic Effects of Nipocalimab on Disease Biomarkers in Patients With Moderate-to-Severe Active Sjögren's Disease: Results From a Multicenter, Randomized, Double-Blinded, Placebo-Controlled Phase 2 Study	Thursday, June 12 12:00-13:30
Lupus		
LupusNet RWE Study Abstract		
POS1333	From Onset to Insights: Longitudinal Assessment of Disease Activity, Flares, and Damage Accrual in Patients with SLE Across 5 Registries in the Lupus Federated Data Network (LupusNet)	Saturday, June 14 10:15-11:45
Molecular Subtypes Study Abstract		
POS0323	Validation and Characterization of Six Distinct SLE Molecular Subtypes Using Two Large Patient Cohorts and Multi-Omics Platforms	Friday, June 13 10:06-10:12
GLADEL 2.0 Study Abstracts		
POS0841	The Renal Activity Index for Lupus Identifies and Predicts Complete Renal Remission or Absence of Kidney Involvement in Systemic Lupus Erythematosus	Thursday, June 12 12:00-13:30
POS1216	Effect of Gender and Follow-up Time in Damage Accrual: Data From a Latin America Lupus Cohort	Saturday, June 14 10:15-11:45

*Encore abstract

Rheumatic diseases		
Drug-Drug Interactions Study Abstract		
POS0917	Assessment of Pharmacokinetic and Pharmacodynamic Drug-Drug Interactions With Nipocalimab and Relevance to Patients With Rheumatic Diseases	Thursday, June 12 14:45-15:45

Johnson & Johnson sponsored icotrokinra studies

Abstract Number	Title	Presentation time (CEST)
Psoriasis		
ICONIC-LEAD Study Abstract		
POS0841 *	Icotrokinra, a Targeted Oral Peptide That Selectively Blocks the Interleukin-23–Receptor, for the Treatment of Moderate-to-Severe Plaque Psoriasis: Results Through Week 24 of the Phase 3, Randomized, Double-Blind, Placebo-Controlled ICONIC-LEAD Trial	Friday, June 13 14:45-15:45
ICONIC-TOTAL Study Abstract		
POS0917 *	Treatment of Plaque Psoriasis Involving High-Impact Areas With Icotrokinra, a Targeted Oral Peptide That Selectively Binds the Interleukin-23–Receptor: Results Through Week 16 of the Phase 3, Randomized, Double-blind, Placebo-Controlled ICONIC-TOTAL Trial	Friday, June 13 14:45-15:45
FRONTIER 1&2 Study Abstract		
POS1071*	Pharmacodynamic Response of JNJ-77242113 in Serum and Skin of Patients With Moderate-to-Severe Psoriasis: 1-Year Results From FRONTIER 1 & 2	Friday, June 13 14:45-15:45
Psoriatic arthritis		
ICONIC PsA-1, ICONIC PsA-2 Study Abstract		
POS1072	Icotrokinra, a Novel Targeted Oral Peptide, in Patients with Psoriatic Disease: Exploratory Assessments From a Phase 2 Psoriasis Study Informing a Phase 3 Clinical Program in Psoriatic Arthritis	Saturday, June 14 10:15-11:45

*Encore abstract

Johnson & Johnson sponsored JNJ-4703 studies

Abstract Number	Title	Presentation time (CEST)
Rheumatoid arthritis		
Safety, Tolerability, and Activity in RA Study Abstract		
POS0597	Safety, Tolerability, and Activity of JNJ-67484703 in Participants With Active Rheumatoid Arthritis: Results of a Multicenter, Double-Blind, Placebo-Controlled, Randomized, Multiple-Dose Phase 1b Study	Wednesday, June 11 15:30-16:30
PARIS Study Abstract		
POS0094	Pharmacodynamic Activity of JNJ-67484703 in Rheumatoid Arthritis, Ulcerative Colitis and Sjogren's disease (PARIS): Results of a Phase II Proof of Biology Trial	Thursday, June 12 12:12-12:18

Johnson & Johnson sponsored SIMPONI® (golimumab) studies

Abstract Number	Title	Presentation time (CEST)
Polyarticular juvenile idiopathic arthritis		
BiKeR Study Abstract		
POS0289	Safety and Effectiveness of Golimumab for the Treatment of Polyarticular Juvenile Idiopathic Arthritis: Insights From the BiKeR Registry	Friday, June 13 12:30-12:36

Other Johnson & Johnson sponsored studies

Abstract Number	Title	Presentation time (CEST)
Psoriatic arthritis		
MONITOR Study Abstract		
OP0093	Effectiveness of Combination csDMARD Therapy in Psoriatic Arthritis Using Data From the MONITOR-PsA Cohort	Oral presentation Wednesday, June 11 17:10-17:20
POS0106	Real-World Treat-to-Target Strategy in Psoriatic Arthritis: 48-Week Results From the MONITOR-PsA Cohort	Thursday, June 12 12:24-12:30
Ankylosing spondylitis and multiple disease areas		
POS1129	Identification of Tissue-Associated Remodeling Endotypes in Rheumatic Disease Cohorts	Friday, June 13 14:45-15:45
POS0236	Comparative Immunology of Entheseal Anchorage Sites Between Spine, Hip and Knee Demonstrates up to 50-Fold Greater IL-23 Induction From Axial Enthesis Bone: A New Angle on the Failure of IL-23 Blockade in Ankylosing Spondylitis	Friday, June 13 15:27-15:33

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*Encore abstract

TREMFYA® (GUSELKUMAB) MPORTANT 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
- 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 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® (USTEKINUMAB) 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.

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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 a way 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.

SIMPONI® (GOLIMUMAB) IMPORTANT SAFETY INFORMATION

Serious Infections

SIMPONI® (golimumab) is a prescription medicine. SIMPONI® can lower your ability to fight infections. There are reports of serious infections caused by bacteria, fungi, or viruses that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor will test you for TB before starting SIMPONI® and will monitor you for signs of TB during treatment. Tell your doctor if you have been in close contact with people with TB. Tell your doctor if you have been in a region (such as the Ohio and Mississippi River Valleys and the Southwest) where certain fungal infections like histoplasmosis or coccidioidomycosis are common.

You should not start SIMPONI® if you have any kind of infection. Tell your doctor if you are prone to or have a history of infections or have diabetes, HIV or a weak immune system. You should also tell your doctor if you are currently being treated for an infection or if you have or develop any signs of an infection such as:

- fever, sweat, 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 than normal
- feel very tired

Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with SIMPONI® and during treatment with SIMPONI®. Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are taking SIMPONI®. People who had a negative TB skin test before receiving SIMPONI® have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking SIMPONI®:

- cough that does not go away
- weight loss
- low grade fever
- loss of body fat and muscle (wasting)

CANCER

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. For children and adults taking TNF blockers, including SIMPONI®, the chances for getting lymphoma or other cancers may increase. Hepatosplenic T-cell lymphoma, a rare and fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking other TNF blockers with azathioprine or 6-mercaptopurine. You should tell your doctor if you have had or develop lymphoma or other cancers.

Some people treated with SIMPONI® have developed certain kinds of skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with SIMPONI®, tell your doctor.

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USE WITH OTHER DRUGS

Tell your doctor about all the medications you take including ORENCIA® (abatacept), KINERET® (anakinra), ACTEMRA® (tocilizumab), RITUXAN® (rituximab), or another TNF blocker, or if you are scheduled to or recently received a vaccine. People taking SIMPONI® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer).

HEPATITIS B INFECTION

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF-blocker medicines, such as SIMPONI®. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI®. Tell your doctor if you know or think you may be a carrier of hepatitis B virus or if you experience signs of hepatitis B infection, such as:

- feel very tired
- dark urine
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- clay-colored bowel movements
- fever
- chills
- stomach discomfort
- skin rash

HEART FAILURE

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI®. If you develop new or worsening heart failure with SIMPONI®, you may need treatment in a hospital, and it may result in death. Your doctor will closely monitor you if you have heart failure. Tell your doctor right away if you get new or worsening symptoms of heart failure like shortness of breath, swelling of your lower legs or feet, or sudden weight gain.

NERVOUS SYSTEM PROBLEMS

Rarely, people using TNF blockers, including SIMPONI®, can have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you have symptoms like vision changes, weakness in your arms or legs, or numbness or tingling in any part of your body.

IMMUNE SYSTEM PROBLEMS

Rarely, people using TNF blockers have developed lupus-like symptoms. Tell your doctor if you have any symptoms such as a rash on your cheeks or other parts of the body, sensitivity to the sun, new joint or muscle pain, becoming very tired, chest pain or shortness of breath, swelling of the feet, ankles, and/or legs.

LIVER PROBLEMS

Serious liver problems can happen in people using TNF blockers, including SIMPONI®. Contact your doctor immediately if you develop symptoms such as feeling very tired, skin or eyes look yellow, poor appetite or vomiting, or pain on the right side of your stomach.

BLOOD PROBLEMS

Low blood counts have been seen with SIMPONI®. If this occurs, your body may not make enough blood cells to help fight infections or help stop bleeding. Your doctor will check your blood counts before and during treatment. Tell your doctor if you have signs such as fever, bruising, bleeding easily, or paleness.

OTHER CONSIDERATIONS TO TELL YOUR DOCTOR

Tell your doctor if you are allergic to rubber or latex. The needle cover contains dry natural rubber. Tell your doctor if yo u are pregnant, planning to become pregnant or are breastfeeding or have a baby and were using SIMPONI® during pregnancy. Tell your baby's doctor before your baby receives any vaccine because of an increased risk of infection for up to 6 months after birth.

ALLERGIC REACTIONS

Allergic reactions can happen in people who use TNF-blocker medicines, including SIMPONI®. Tell your doctor if you have any symptoms of an allergic reaction while taking SIMPONI® such as hives, swollen face, breathing trouble, or chest pain. Some re actions can be serious and life-threatening.

Common side effects of SIMPONI® include: upper respiratory tract infection, reaction at site of injection, and viral infections.

PSORIASIS

New or worse psoriasis symptoms may occur. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus.

Please read the full Prescribing Information, including Medication Guide, for SIMPONI® 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.

IMAAVY™ (NIPOCALIMAB-AAHU) IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMAAVY™?

IMAAVY™ is a prescription medicine that may cause serious side effects, including:

- **Infections** are a common side effect of IMAAVY™ that can be serious. Receiving IMAAVY™ may increase your risk of infection. Tell your healthcare provider right away if you have any of the following infection symptoms:
    - fever
    - chills
    - shivering
    - cough
    - sore throat
    - fever blisters
    - burning when you urinate
- **Allergic (hypersensitivity) reactions** may happen during or up to a few weeks after your IMAAVY™ infusion. Get emergency medical help right away if you get any of these symptoms during or after your IMAAVY™ infusion:
    - a swollen face, lips, mouth, tongue, or throat
    - difficulty swallowing or breathing
    - itchy rash (hives)
    - chest pain or tightness

- **Infusion-related reactions** are possible. Tell your healthcare provider right away if you get any of these symptoms during or a few days after your IMAAVY™ infusion:
    - headache
    - rash
    - nausea
    - fatigue
    - dizziness
    - chills
    - flu-like symptoms
    - redness of skin

Do not receive IMAAVY™ if you have a severe allergic reaction to nipocalimab-aahu or any of the ingredients in IMAAVY™. Reactions have included angioedema and anaphylaxis.

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

- ever had an allergic reaction to IMAAVY™.
- have or had any recent infections or symptoms of infection.
- have recently received or are scheduled to receive an immunization (vaccine).

People who take IMAAVY™ should not receive live vaccines.
- are pregnant, plan to become pregnant, or are breastfeeding. It is not known whether IMAAVY™ will harm your baby.

Pregnancy Safety Study. There is a pregnancy safety study for IMAAVY™ if IMAAVY™ is given during pregnancy or you become pregnant while receiving IMAAVY™. Your healthcare provider should report IMAAVY™ exposure by contacting Janssen at 1-800-526-7736 or www.IMAAVY.com.

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

The most common side effects of IMAAVY™ include: respiratory tract infection, peripheral edema (swelling in your hands, ankles, or feet), and muscle spasms.

These are not all the possible side effects of IMAAVY™. Call your doctor for medical advice about side effects. **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.**

Please see the full Prescribing Information and Medication Guide for IMAAVY™ and discuss any questions you have with your doctor.

Dosage Form and Strengths: IMAAVY™ is supplied as a 300 mg/1.62 mL and a 1,200 mg/6.5 mL (185 mg/mL) single-dose vial per carton for intravenous injection.