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NEWS RELEASE

U.S. FDA approves TREMFYA® (guselkumab), the first and only IL-23 inhibitor offering both subcutaneous and intravenous induction options, for adult patients with moderately to severely active Crohn's disease

2025-03-20

TREMFYA® is the only IL-23i to demonstrate clinical remission and endoscopic response, both at one year, with a fully subcutaneous induction regimen

Supported by data from the GALAXI study, TREMFYA® is the only IL-23i to show superiority versus STELARA® in all pooled endoscopic endpoints within a double-blinded registrational trial

TREMFYA® approval in Crohn's disease builds upon recent ulcerative colitis FDA approval, marking the fourth indication for this dual-acting IL-23i in the U.S.

HORSHAM, Pa., March 20, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) has approved TREMFYA® (guselkumab), the first and only IL-23 inhibitor offering both subcutaneous (SC) and intravenous (IV) induction options, for the treatment of adults with moderately to severely active Crohn's disease (CD), a chronic inflammatory condition of the gastrointestinal tract.[1] This milestone builds upon the FDA approval of TREMFYA® in moderately to severely active ulcerative colitis (UC), one of two main forms of inflammatory bowel disease (IBD),[2] which impacts the lives of nearly three million Americans.[3] TREMFYA® is the first and only approved fully-human, dual-acting monoclonal antibody that blocks IL-23 while also binding to CD64, a receptor on cells that produce IL-23. IL-23 is a cytokine secreted by activated monocyte/macrophages and dendritic cells that is known to be a driver of immune-mediated diseases including CD.[4,5,6,7,8]

"Despite the progress in the management of Crohn's disease, many patients experience debilitating symptoms and

are in need of new treatment options," said Remo Panaccione, MD, FRCPC, Professor of Medicine and the Director of the Inflammatory Bowel Disease Unit at the University of Calgary and lead investigator of the Phase 3 GRAVITI study. "The approval of TREMFYA offers an IL-23 inhibitor that has shown robust rates of endoscopic remission with both subcutaneous and intravenous induction regimens. Importantly, the fully subcutaneous regimen offers choice and flexibility for patients and providers that have not been available before."

This approval is supported by results from multiple rigorous Phase 3 trials evaluating more than 1,300 patients with moderately to severely active CD who failed or were intolerant to conventional therapy (i.e. corticosteroids or immunomodulators) or biologics.[6] The GRAVITI study evaluated TREMFYA® SC induction and maintenance therapy versus placebo. Data from the GALAXI clinical program showed TREMFYA® was superior to STELARA® in all pooled endoscopic endpoints, the only IL-23 inhibitor to achieve this in a double-blinded registrational program. The comprehensive results from these Phase 3 studies demonstrated the robust efficacy of SC or IV TREMFYA® in achieving clinical and endoscopic endpoints. Highlights from these pivotal studies showed:[6]

Week 12 Results	GRAVITI	GALAXI 2	GALAXI 3
	TREMFYA® 400 mg SC induction at Weeks 0, 4 and 8 vs. placebo	TREMFYA® 200 mg IV induction at Weeks 0, 4 and 8 vs. placebo	TREMFYA® 200 mg IV induction at Weeks 0, 4 and 8 vs. placebo
Clinical remission	56% vs. 22% (p<0.001)	47% vs. 20% (p<0.001)	47% vs. 15% (p<0.001)
Endoscopic response	34% vs. 15% (p<0.001)	36% vs. 9% (p<0.001)	34% vs. 13% (p<0.001)
Week 48 Results	GRAVITI		
	TREMFYA® 100 mg SC maintenance q8w starting at Week 16 vs. placebo	TREMFYA® 200 mg SC maintenance q4w starting at Week 12 vs. placebo	
Clinical remission	59% vs. 17%	65% vs. 17%	
Endoscopic response	39% vs. 5%	48% vs. 5%	
Endoscopic remission	31% vs. 6%	40% vs. 6%	
Deep remission (clinical & endoscopic remission)[9]	26% vs. 4%	34% vs. 4%	

"TREMFYA is the first and only IL-23 inhibitor that offers a fully subcutaneous treatment option for moderately to severely active Crohn's disease. With the approval of TREMFYA, it is now possible to achieve meaningful improvements in clinical and endoscopic outcomes with the flexibility of self-administration from the start," said Chris Gasink, MD, Vice President, Medical Affairs, Gastroenterology & Autoantibody, Johnson & Johnson Innovative Medicine. "TREMFYA provides people living with Crohn's disease and their healthcare providers a new treatment option that is supported by data from multiple Phase 3 studies, including pooled analyses showing statistical superiority versus STELARA across four endoscopic or combined clinical and endoscopic endpoints."

TREMFYA® dosing in the treatment of moderately to severely active CD:[6]

- The recommended SC induction dosage is 400 mg (given as two consecutive injections of 200 mg each, dispensed in one Induction Pack) at Weeks 0, 4 and 8. TREMFYA® is also available in a 200 mg prefilled syringe. For the IV induction option, 200 mg IV infusions are administered at Weeks 0, 4 and 8.
- Recommended maintenance dosage is 100 mg administered by SC injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by SC injection at Week 12, and every 4 weeks thereafter. Healthcare providers are instructed to use the lowest effective recommended dosage to maintain therapeutic response.

Johnson & Johnson is committed to supporting access to all its treatments, including offering a patient support program called TREMFYA® withMe. For commercially insured patients, adults who are prescribed TREMFYA® for CD may be eligible to receive their first induction treatment in as little as 24 hours through TREMFYA® withMe.

This approval marks the fourth indication for TREMFYA® in the U.S., following moderate-to-severe plaque psoriasis in July 2017, active psoriatic arthritis in July 2020 and moderately to severely active UC in September 2024,[6] underscoring Johnson & Johnson's long-standing legacy in innovation and commitment to patients living with chronic immune-mediated diseases, including IBD. In November 2024, Johnson & Johnson **submitted** a supplemental Biologics License Application (sBLA) to the FDA seeking approval of a SC induction regimen of TREMFYA® for the treatment of adults with moderately to severely active UC, based on results of the Phase 3 ASTRO study.

Editor's Notes:

a) CD64+ cells are the predominant source of IL-23 in CD. Cells not expressing CD64 may also contribute to IL-23 production but to a lesser extent.[1,3]
b) "Only" based on approved selective IL-23 inhibitors for moderately to severely active CD as of March 2025.[6,7,8]
c) Based on in vitro studies in an inflammatory monocyte model.[4]
d) Moderately to severely active CD was defined as a Crohn's Disease Activity Index (CDAI) score of ≥220 and a Simple Endoscopic Score for Crohn's Disease (SES-CD) of ≥6 (or ≥4 for subjects with isolated ileal disease).[6]
e) Clinical remission was defined as a CDAI score of <150.[6]
f) Endoscopic response is defined as >50% improvement from baseline in SES-CD score.[6]
g) Endoscopic remission was defined as an SES-CD score ≤4 and at least a 2-point reduction from baseline and no subscore greater than 1 in any individual component.[6]
h) q4w is defined as every four weeks.[6]
i) q8w is defined as every eight weeks.[6]
j) Dr. Panaccione is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

ABOUT THE GRAVITI STUDY (**NCT05197049**)

GRAVITI is a randomized, double-blind, placebo-controlled Phase 3 study to evaluate guselkumab SC induction therapy (400 mg at Weeks 0, 4, and 8) in patients with moderately to severely active Crohn's disease who experienced an inadequate response or failed to tolerate conventional therapy (i.e., corticosteroids or immunomodulators) or biologic therapy (TNF antagonists or vedolizumab).[10] Patients received guselkumab 400 mg SC q4w (x3) followed by guselkumab 200 mg SC q4w; or guselkumab 400 mg SC q4w (x3) followed by guselkumab 100 mg SC q8w; or placebo. The maintenance doses in GRAVITI (200 mg SC q4w and 100 mg SC q8w) are the same as those evaluated in the Phase 3 GALAXI 2 and GALAXI 3 studies that evaluated the efficacy and safety of IV induction followed by SC maintenance therapy in patients with moderate to severely active Crohn's disease. Similar to GALAXI, GRAVITI employed a treat-through design, in which patients were randomized to guselkumab at Week 0 and remained on that regimen throughout the study, regardless of clinical response status at the end of induction. Participants randomized to placebo were able to receive guselkumab (400 mg SC q4w x3 ➔ 100 mg SC q8w) if rescue criteria were met at Week 16.[10]

ABOUT THE GALAXI PROGRAM (**NCT03466411**)

GALAXI is a randomized, double-blind, placebo-controlled, active-controlled (ustekinumab), global, multicenter Phase 2/3 program designed to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active Crohn's disease with inadequate response/intolerance to conventional therapies (corticosteroids or immunomodulators) and/or biologics (TNF antagonists or vedolizumab).[11] GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3).[11] Each GALAXI study employed a treat-through design in which participants remained on the treatment to which they were initially randomized and includes a long-term extension study that will assess clinical, endoscopic, and safety outcomes with guselkumab through a total of five years. Patients received guselkumab 200 mg intravenous induction at Weeks 0, 4 and 8 followed by guselkumab 200 mg subcutaneous maintenance every 4 weeks; or guselkumab 200 mg intravenous induction at Weeks 0, 4 and 8, followed by guselkumab 100 mg subcutaneous maintenance every 8 weeks; or a biologic active control; or placebo. Participants randomized to placebo were able to receive ustekinumab if clinical response was not met at Week 12. Of the 873 individuals pooled across the GALAXI 2 & 3 dataset, 456 (52 percent) had prior history of inadequate response to biologics, 365 (42 percent) were biologic-naïve and 52 (6 percent) were biologic experienced without documented inadequate response or intolerance.[12] The GALAXI 2 and GALAXI 3 studies were the first-ever double-blind registrational head-to-head clinical trials to demonstrate superiority versus ustekinumab in Crohn's disease, showing guselkumab was superior to ustekinumab in all endoscopic-based endpoints when analyzed with pooled data.

ABOUT CROHN'S DISEASE

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated three

million Americans.[3] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other environmental factors.[1] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Currently no cure is available for Crohn's disease.[3]

ABOUT TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first approved fully-human, dual-acting monoclonal antibody designed to neutralize inflammation at the cellular source by blocking IL-23 and binding to CD64 (a receptor on cells that produce IL-23). Findings for dual-acting are limited to in vitro studies that demonstrate guselkumab binds to CD64, which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model. The clinical significance of this finding is not known.

TREMFYA® is a prescription medicine approved in the U.S. to treat:

- adults with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.
- adults with moderately to severely active Crohn's disease.

TREMFYA® is approved in Europe, Canada, Japan, and a number of other countries for the treatment of adults with moderate-to-severe plaque psoriasis and for the treatment of adults with active psoriatic arthritis.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®. For more information, visit: **www.tremfya.com**.

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:

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o fainting, dizziness, feeling lightheaded (low blood pressure)

o trouble breathing or throat tightness

- swelling of your face, eyelids, lips, mouth, tongue or throat
- 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.

ABOUT STELARA® (ustekinumab)

STELARA® (ustekinumab), a human interleukin (IL)-12 and IL-23 antagonist, is a prescription medicine approved in the United States to treat.[13]

- adults and children 6 years and older with moderate to severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years and older with active psoriatic arthritis.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to 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 **https://www.fda.gov/medwatch** or call 1-800-FDA-1088.

ABOUT JOHNSON & JOHNSON

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity. Learn more at **https://www.jnj.com/** or at **www.innovativemedicine.jnj.com**.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding TREMFYA®. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Scientific Affairs, LLC, Janssen Biotech, Inc., Janssen-Cilag International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and

of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at **www.sec.gov**, **www.jnj.com** or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Scientific Affairs, LLC, Janssen Biotech, Inc., Janssen-Cilag International NV nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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[10] National Institutes of Health: **Clinicaltrials.gov**. A study of guselkumab subcutaneous therapy in participants with moderately to severely active Crohn's disease (GRAVITI). Identifier: NCT05197049. Available at: **https://classic.clinicaltrials.gov/ct2/show/NCT05197049**. Accessed February 2025.

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[13] STELARA® Prescribing information. Available at: **https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf** Accessed March 2025.

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