



## **News Release**

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## **JANSSEN DEMONSTRATES STRONG COMMITMENT TO ADVANCING SCIENCE OF INFLAMMATORY BOWEL DISEASES WITH ROBUST SELECTION OF DATA PRESENTATIONS AT 14<sup>TH</sup> CONGRESS OF ECCO**

*New Phase 3 Data Evaluating STELARA® (ustekinumab) Maintenance Therapy in Patients with Moderate to Severe Ulcerative Colitis Featured in Plenary Session*

SPRING HOUSE, PENNSYLVANIA, February 25, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced 18 company-sponsored abstracts will be presented at the [14th Congress of the European Crohn's and Colitis Organisation](#) (ECCO) taking place in Copenhagen, Denmark from March 6-9. Highlights include six company-sponsored oral or digital oral presentations, including new data from the Phase 3 UNIFI study evaluating the efficacy and safety of STELARA® (ustekinumab) maintenance therapy in patients with moderate to severe ulcerative colitis (UC), which will be presented during the Plenary Session on March 9.

"This year marks the largest showing of data from our inflammatory bowel disease portfolio of products at ECCO, a reflection of our continued leadership and unwavering commitment to addressing unmet needs for people living with IBD," said Scott E. Plevy, M.D., Gastroenterology Disease Area and IL-23 Pathway Leader, Janssen Research &

Development, LLC. “We are excited to present new Phase 3 maintenance data for STELARA in ulcerative colitis which are the basis of our pending regulatory applications in the European Union, U.S. and Canada.”

A listing of abstracts is provided in the table below. Notable data presentations at ECCO include the following:

*New STELARA data in ulcerative colitis*

- Results from the Phase 3 UNIFI study evaluating the efficacy and safety of STELARA as a maintenance therapy in patients with moderate to severe ulcerative colitis who were in clinical response to a single intravenous induction of STELARA will be presented during a plenary session. These data were included in the recent [supplemental Biologics License Application](#) submission to the U.S. Food and Drug Administration and [Group Type II Variation Application](#) to the European Medicines Agency. ([Abstract OP37](#))
- Additional data from the Phase 3 UNIFI study evaluating the effects of STELARA induction therapy on endoscopic healing (EH), histologic healing (HH) and combined histo-endoscopic mucosal healing (HEMH), in patients with moderate to severe ulcerative colitis will be presented as a digital oral. UNIFI is the first Phase 3 study to measure the effects of biologic therapy on a combined EH and HH endpoint in patients with UC. Mucosal healing assesses how the colon is responding both histologically and endoscopically to therapy and both have been associated with improved, long-term clinical outcomes and a major therapeutic goal in treating patients with ulcerative colitis. ([Abstract DOP71](#))

*New STELARA data in Crohn’s disease*

- Results from the Phase 3 IM-UNITI maintenance study evaluating efficacy of STELARA after one year of maintenance therapy (i.e. at week 56, rather than the original week 44 primary endpoint) in patients with moderate to severe Crohn’s disease will be shared as a poster presentation. ([Abstract P343](#))

<b>Abstract No.</b>	<b>Title</b>	<b>Date/Time</b>
<a href="#">OP13</a>	Molecular response to ustekinumab in moderate-to-severe ulcerative colitis by serum protein and biopsy gene expression analysis: Results from the UNIFI Phase 3 induction study	Oral presentation Friday, March 8, 2019 8:30 AM - 10:30 AM
<a href="#">P347</a>	New-onset autoimmune disorders, primarily psoriasis, in anti-TNF biologic exposed paediatric patients: the DEVELOP experience	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P446</a>	Dose escalation with originator infliximab is more common than standard dosing in paediatric IBD: the DEVELOP experience	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P382</a>	Combination therapy with TNF-inhibitors and immunomodulators are associated with shorter duration to first serious infection: the DEVELOP experience	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P651</a>	Disease severity and intensity of therapy predicts serious adverse events in paediatric ulcerative colitis: the DEVELOP experience	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P406</a>	General health status in patients with moderate to severe ulcerative colitis receiving ustekinumab: results from the Phase 3 UNIFI induction and maintenance studies	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P681</a>	Ustekinumab therapy induced clinically meaningful improvement and remission as measured by the Inflammatory Bowel Disease Questionnaire: Results from the phase 3 UNIFI induction and maintenance studies	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P312</a>	Efficacy in biologic failure and non-biologic-failure populations in a Phase 3 study of ustekinumab in moderate-severe ulcerative colitis: UNIFI	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P477</a>	Clinical remission by legacy vs. FDA definitions: definition justification and results from UNIFI Study	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P317</a>	Characterisation of patients with delayed response to ustekinumab for Crohn's disease	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P680</a>	Long-term efficacy of ustekinumab with and without concomitant immunosuppressants for Crohn's disease: results from IM-UNITI long-term extension through 2 years	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P343</a>	Efficacy of ustekinumab in Crohn's disease at maintenance Week 56: IM-UNITI study	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">P311</a>	Pharmacokinetics and exposure-response relationships of intravenously administered ustekinumab during induction treatment in patients with ulcerative colitis: Results from the UNIFI induction study	Poster presentation Friday, March 8, 2019 12:30 PM - 1:30 PM
<a href="#">DOP47</a>	Sustained remission in patients with moderate to severe ulcerative colitis: Results from the Phase 3 UNIFI maintenance study	Digital oral presentation Friday, March 8, 2019 5:20 PM - 6:20 PM

<a href="#">DOP71</a>	Effects of ustekinumab induction therapy on endoscopic and histological healing in the UNIFI Phase 3 study in ulcerative colitis	Digital oral presentation Friday, March 8, 2019 5:20 PM - 6:20 PM
<a href="#">DOP54</a>	Efficacy and safety of ustekinumab through Week 16 in patients with moderate-to-severe ulcerative colitis randomised to ustekinumab: results from the UNIFI induction trial	Digital oral presentation Friday, March 8, 2019 5:20 PM - 6:20 PM
<a href="#">OP36</a>	A colonic gene expression signature predicts non-response to anti-inflammatory therapies in inflammatory bowel disease	Oral presentation Saturday, March 9, 2019 10:50 AM - 12:20 PM
<a href="#">OP37</a>	Efficacy and safety of ustekinumab as maintenance therapy in ulcerative colitis: Week 44 results from UNIFI	Oral presentation Saturday, March 9, 2019 10:50 AM - 12:20 PM

### **About Inflammatory Bowel Diseases**

More than five million people worldwide are living with Crohn’s disease and ulcerative colitis—collectively known as IBD.<sup>1</sup> Crohn’s disease most commonly affects the end of the small bowel (the ileum) and the beginning of the colon, but it may affect any part of the gastrointestinal (GI) tract, from the mouth to the anus. Ulcerative colitis is limited to the colon, also called the large intestine. Symptoms of Crohn’s disease can vary but may include abdominal cramps and pain, frequent diarrhea, rectal bleeding, weight loss and fever. There is currently no cure for Crohn’s disease.<sup>2</sup> Symptoms of ulcerative colitis can vary but may include looser and more urgent bowel movements, bloody stool, crampy abdominal pain, loss of appetite and fatigue. There is currently no cure for ulcerative colitis.<sup>3</sup>

### **About STELARA® (ustekinumab)**

STELARA® (ustekinumab), a human IL-12 and IL-23 antagonist, is approved in the United States for the treatment of: 1) adults and children 12 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; 2) adult patients (18 years or older) with active psoriatic arthritis, used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active Crohn’s disease who have failed or were intolerant to immunomodulators or corticosteroids; or failed or were intolerant to anti-TNF therapies.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

## **Important Safety Information**

STELARA<sup>®</sup> is a prescription medicine that affects your immune system. STELARA<sup>®</sup> can increase your chance of having serious side effects including:

### **Serious Infections**

STELARA<sup>®</sup> may lower your ability to fight infections and may increase your risk of infections. While taking STELARA<sup>®</sup>, 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<sup>®</sup> and watch you closely for signs and symptoms of TB during treatment with STELARA<sup>®</sup>.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA<sup>®</sup>.

You should not start taking STELARA<sup>®</sup> if you have any kind of infection unless your doctor says it is okay.

### **Before starting STELARA<sup>®</sup>, 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
- 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). 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.

### **Reversible posterior leukoencephalopathy syndrome (RPLS)**

RPLS is a rare condition that affects the brain and can cause death. The cause of RPLS is not known. If RPLS 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 RPLS.
- 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®.
- are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk. Talk to your doctor about the best way to feed your baby if you receive STELARA®.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

**When prescribed STELARA®:**

- Use STELARA® exactly as your doctor tells you to. STELARA® is intended for use under the guidance and supervision of your doctor.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 12 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:** upper respiratory infections, headache, and tiredness **in psoriasis** patients; joint pain and nausea **in psoriatic arthritis patients**; and upper respiratory infections, redness at the injection site, vaginal yeast infections, itching, urinary tract infections, and vomiting **in Crohn's disease** patients. 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 read the [Full Prescribing Information](#), including the [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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal).

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1. World IBD Day. Home. Available at <http://www.worldibdday.org/index.html>. Accessed February 4, 2019.



2. Crohn's & Colitis Foundation of America. What is Crohn's Disease? Available at <http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-crohns-disease/>. Accessed February 2019.
3. Crohn' & Colitis Foundation of America. What is Ulcerative Colitis? Available at <http://www.crohnscolitisfoundation.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/>. Accessed February 2019.