

# **News Release**

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# JANSSEN TO PRESENT NEW INFLAMMATORY BOWEL DISEASE DATA AT DIGESTIVE DISEASE WEEK MEETING

Fifteen Janssen abstracts accepted for presentation, showcasing commitment to gastroenterology

Horsham, PA (May 16, 2016) – Janssen Biotech, Inc. announced today that 15 abstracts will be presented at the 2016 Digestive Disease Week (DDW) annual meeting, taking place May 21-24 in San Diego, California. Data from the Janssen Gastroenterology portfolio of injection and infusion biologic therapies will include a pivotal Phase 3 (IM-UNITI) STELARA® (ustekinumab) maintenance therapy study for adult patients with moderate to severe Crohn's disease, an open label study investigating safety and efficacy outcomes for SIMPONI® (golimumab) in pediatric patients with ulcerative colitis, and safety data from a cohort of elderly Crohn's Disease patients from the REMICADE® TREAT registry.

"At Janssen, we are proud of our leadership position in Gastroenterology and are pleased to be presenting our breadth of new data at DDW," said Andrew Greenspan, M.D., Vice President, Janssen Scientific Affairs, LLC. "After more than 20 years focused on Inflammatory Bowel Disease, we understand that significant unmet medical need still exists and are hopeful that our research can potentially lead to novel therapeutics that can change lives for the better."

#### Janssen Abstracts to Be Presented During DDW 2016

Abstracts can be accessed on the DDW 2016 annual meeting website at https://ddw2016.abstractcentral.com/login.

### STELARA® (ustekinumab)

- Molecular Response to Ustekinumab in Moderate-to-Severe Crohn's Disease by Serum Protein Analysis: Results from UNITI-1 Induction, UNITI-2 Induction, and IM-UNITI Maintenance Studies (Presentation Sa1837)
  - Poster presentation: Saturday, May 21, 9:30 am 4:00 pm
- Pharmacokinetics and Exposure-Response Relationships of Ustekinumab During IV Induction and SC Maintenance Treatment of Patients With Crohn's Disease With Ustekinumab: Results From the UNITI-1, UNITI-2, and IM-UNITI Studies (Presentation Su1923)
  - o Poster presentation: Saturday, May 21, 9:30 am 4:00 pm

- A Phase 3 Randomized, Multicenter, Double-Blind, Placebo-Controlled Study of Ustekinumab Maintenance Therapy in Moderate-Severe Crohn's Disease Patients: Results From IM-UNITI (Presentation 768)
  - o Oral presentation: Monday, May 23, 5:16 pm 5:30 pm
- Assessment of Serum C-Reactive Protein, Fecal Lactoferrin, and Fecal Calprotectin in Patients With Moderate-Severely Active Crohns Disease: Results From the IM-UNITI Maintenance Study (Presentation Tu1934)
  - o Poster presentation: Tuesday, May 24, 9:30 am 4:00 pm
- Ustekinumab Improves General Health Status and Disease-Specific Health Related Quality of Life of Patients With Moderate to Severe Crohn's Disease: Results from the UNITI and IM-UNITI Phase 3 Clinical Trials (Presentation Tu2006)
  - Poster presentation: Tuesday, May 24, 9:30 am 4:00 pm

# SIMPONI® (golimumab)

- Population Pharmacokinetic Modeling Analysis of Golimumab in Adult Patients With Moderately to Severely Active Ulcerative Colitis (Presentation Sa1935)
  - o Poster presentation: Saturday, May 21, 9:30 am 4:00 pm
- Pharmacokinetics and Exposure-Response Relationships of Golimumab in Pediatric Patients With Moderate to Severe Ulcerative Colitis: Results From a Multicenter Open Label Study (Presentation Su1923)
  - Poster presentation: Sunday, May 22, 9:30 am 4:00 pm
- The Role of the Microbiome in Clinical Response to Golimumab in Ulcerative Colitis (Presentation Su1217)
  - o Poster presentation: Sunday, May 22, 9:30 am 4:00 pm
- Delayed Response to Golimumab Therapy: UC Patient Characteristics and Long-term Clinical Outcome: Post-Hoc Analyses From the PURSUIT Program (Presentation Mo1794)
  - o Poster presentation: Monday, May 23, 9:30 am 4:00 pm
- Safety, Efficacy, and Pharmacokinetics of Golimumab in Patients with Moderately to Severely Active Ulcerative Colitis: PURSUIT-SC Long Term Extension (Presentation Mo1790)
  - o Poster presentation: Monday, May 23, 9:30 am 4:00 pm
- A Multi-Center Open-Label Study Assessing Pharmacokinetics, Efficacy, and Safety of Subcutaneous Golimumab in Pediatric Patients With Moderately-Severely Active Ulcerative Colitis (Presentation #631)
  - o Oral presentation: Monday, May 23, 10:30 am 10:45 am

# **REMICADE®** (infliximab)

- Risk Factors for Serious Infections in Elderly Patients Receiving Infliximab and Other Crohn's Disease Therapies: TREAT™ Registry Data (Presentation Mo1800)
  - o Poster presentation: Monday, May 23, 9:30 am 4:00 pm
- Risk of Malignancy in Pediatric Inflammatory Bowel Disease: Results From the DEVELOP Registry (Presentation #629)
  - o Oral presentation: Monday, May 23, 10:00 am 10:15 am

#### **INFLAMMATORY BOWEL DISEASE DATA**

- Evidence of Content Validity and Psychometric Properties of Sf-36 for Measuring Health-Related Quality of Life of Patients With Crohn's Disease (Presentation Su1014)
  - o Poster presentation: Sunday, May 22, 9:30 am 4:00 pm
- Prevalence of Inflammatory Bowel Disease Among Patients With Psoriasis and Incidence of Serious Infections in This Subset: Results From the PSOLAR Registry (Presentation Mo1884)
  - o Poster presentation: Monday, May 23, 9:30 am 4:00 pm

# About Inflammatory Bowel Diseases (IBD)<sup>1</sup>

Inflammatory bowel diseases (IBD) affect approximately 1.6 million Americans, or 1 in 200 people, with the incidence evenly split between ulcerative colitis and Crohn's disease. IBD affects men and women equally and can strike at any age. While both inflammatory bowel diseases have similar symptoms, including diarrhea, abdominal pain and weight loss, Crohn's disease can affect any part of the GI tract, whereas ulcerative colitis is limited to the colon. Although considerable progress has been made in IBD research, investigators do not yet know what causes IBD. There is currently no medical cure for ulcerative colitis or Crohn's disease. <sup>1</sup>

# About STELARA® (ustekinumab)

STELARA<sup>®</sup>, a human interleukin (IL)-12 and IL-23 antagonist, is approved in the United States for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. STELARA<sup>®</sup> is also approved for the treatment of adult patients (18 years or older) with active psoriatic arthritis and can be used alone or in combination with methotrexate (MTX).

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®, which is currently approved for the treatment of moderate to severe plaque psoriasis in 87 countries and psoriatic arthritis in 71 countries.

## **Important Safety Information (U.S.)**

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<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 your phleam
- 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 who has TB

After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above).

STELARA<sup>®</sup> 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. It is not known if people who take STELARA<sup>®</sup> will get any of these infections because of the effects of STELARA<sup>®</sup> on these proteins.

#### **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. Get medical help right away if you have any symptoms such as: feeling faint, swelling of your face, eyelids, tongue, or throat, trouble breathing, throat or chest tightness, or skin rash.

Before receiving STELARA®, tell your doctor 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 vaccine. The viruses used in some types of 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 taking STELARA® or one year after you stop taking 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
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if STELARA® will harm your unborn baby. You and your doctor should decide if you will take STELARA®
- are breast-feeding or plan to breast-feed. It is thought that STELARA® passes into your breast milk. You should not breast-feed while taking STELARA® without first talking to your doctor.

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 prescribed by your doctor
- 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®. Do not try to inject STELARA® yourself until you or your caregiver has been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA<sup>®</sup> include: upper respiratory infections, headache, tiredness, joint pain and nausea. These are not all of the possible side effects with STELARA<sup>®</sup>. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

Please read the <u>Full Prescribing Information</u>, including the <u>Medication Guide</u> for STELARA<sup>®</sup>, and discuss any questions you have with your doctor.

# About SIMPONI® (golimumab)

SIMPONI® is a human monoclonal antibody that targets and neutralizes excess TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage and tissue. SIMPONI® is approved in 67 countries, including the United States where SIMPONI® is approved by the United States Food and Drug Administration (FDA) for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) with the medicine methotrexate, active psoriatic arthritis alone or with the medicine methotrexate, active ankylosing spondylitis and moderately to severely active ulcerative colitis. SIMPONI is available either through the SmartJect® autoinjector/prefilled pen or a prefilled syringe as a subcutaneously administered injection. For more information about SIMPONI® visit <a href="https://www.SIMPONI.com">www.SIMPONI.com</a>.

Janssen Biotech, Inc. discovered and developed SIMPONI<sup>®</sup> and markets the product in the United States. Janssen pharmaceutical companies market SIMPONI in Canada, Central and South America, the Middle East, Africa and Asia Pacific.

In Japan, Indonesia and Taiwan, Janssen Biotech, Inc. licenses distribution rights to SIMPONI® to Mitsubishi Tanabe Pharma Corporation and has retained co-marketing rights in those countries. In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to SIMPONI® to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co., Inc.

The U.S. full prescribing information for SIMPONI® can be accessed at the following link: <a href="http://www.simponi.com/sites/default/files/pdf/prescribing-information.pdf">http://www.simponi.com/sites/default/files/pdf/prescribing-information.pdf</a>.

For further information about SIMPONI® outside of the United States, please consult the relevant official product information applicable to that country location.

### **Important Safety Information (U.S.)**

#### **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<sup>®</sup> 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

· weight loss

muscle aches

warm, red, or painful skin or sores on

your body

- cough diarrhea or stomach pain
- shortness of breath

   burning when you urinate or urinate more than normal
- blood in phlegm feel very tired

#### Cancer

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. For children and adults taking TNF blockers, including SIMPONI<sup>®</sup>, 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.

#### **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<sup>®</sup> 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<sup>®</sup>. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI<sup>®</sup>. 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
- clay-colored bowel movements
- dark urine
- fevers
- skin or eyes look yellow

- little or no appetite
- vomiting
- muscle aches
- chills
- stomach discomfort
- skin rash

#### **Heart Failure**

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI®. 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 or swelling of your lower legs or feet.

## **Nervous System Problems**

Rarely, people using TNF blockers, including SIMPONI<sup>®</sup>, 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.

#### **Liver Problems**

Serious liver problems can happen in people using TNF blockers, including SIMPONI<sup>®</sup>. 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 people using TNF blockers, including SIMPONI<sup>®</sup>. 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 you are pregnant, planning to become pregnant or are breastfeeding or have a baby and were using SIMPONI<sup>®</sup> 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<sup>®</sup>. Tell your doctor if you have any symptoms of an allergic reaction while taking SIMPONI<sup>®</sup> such as hives, swollen face, breathing trouble, or chest pain. Some reactions can be serious and life-threatening.

Common side effects of SIMPONI<sup>®</sup> 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 <u>Full Prescribing Information</u> and <u>Medication Guide</u> for SIMPONI® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call 1-800-FDA-1088.

# About REMICADE® (infliximab)

REMICADE® has more than 22 years of clinical and real-world patient experience and was the first biologic approved for the treatment of Crohn's disease, an inflammatory bowel disease. REMICADE® has received 16 U.S. FDA approvals and has been used to treat more than 2.4 million people worldwide since 1998.

In the U.S., REMICADE<sup>®</sup> is approved for the following indications:

- Reducing signs and symptoms, inhibiting the progression of structural damage and improving physical function in patients with moderately to severely active RA, when administered in combination with methotrexate.
- Reducing signs and symptoms in patients with active ankylosing spondylitis.
- Reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric
  patients with moderately to severely active Crohn's disease who have had an inadequate response to
  conventional therapy.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and
  eliminating corticosteroid use in patients with moderately to severely active UC who have had an
  inadequate response to conventional therapy.
- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function in patients with psoriatic arthritis.
- Treatment of adult patients with chronic severe plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

REMICADE® is unique among available anti-TNF-alpha biologic therapies. It is the only anti-TNF-alpha biologic administered directly by caregivers in the clinic or office setting. REMICADE® is a two-hour infusion administered every 6 or 8 weeks (indication-dependent), following a standard induction regimen that requires treatment at weeks 0, 2 and 6. As a result, REMICADE® patients may require as few as six treatments each year as maintenance therapy.

Janssen Biotech, Inc. discovered and developed REMICADE® and markets the product in the United States. The Janssen Pharmaceutical Companies market REMICADE® in Canada, Central and South America, the Middle East, Africa and Asia Pacific.

In Japan, Indonesia, and Taiwan, Janssen Biotech, Inc. licenses distribution rights to REMICADE® to Mitsubishi Tanabe Pharma Corporation. In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to REMICADE® to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co, Inc.

## **Important Safety Information (U.S.)**

Only your doctor can recommend a course of treatment after checking your health condition. REMICADE® (infliximab) can cause serious side effects such as lowering your ability to fight infections. Some patients, especially those 65 years and older, have had serious infections caused by viruses, fungi or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE®.

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking REMICADE® and azathioprine or 6-mercaptopurine. For children and adults taking TNF blockers, including REMICADE®, the chances of getting lymphoma or other cancers may increase.

You should discuss any concerns about your health and medical care with your doctor.

## What should I tell my doctor before I take REMICADE<sup>®</sup>?

You should let your doctor know if you have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start REMICADE®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, have diabetes or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take REMICADE<sup>®</sup>.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

### Also tell your doctor if you:

- Use the medicines Kineret (anakinra), Orencia (abatacept) or Actemra (tocilizumab) or other medicines called biologics used to treat the same problems as REMICADE<sup>®</sup>.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using REMICADE® during your pregnancy. Tell your baby's doctor about your REMICADE® use before the baby receives any vaccine because of an increased risk of infection for up to 6 months after your last dose of REMICADE® you received during your pregnancy.
- Recently received or are scheduled to receive a vaccine. Adults and children taking REMICADE® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking REMICADE®.

# What should I watch for and talk to my doctor about before or while taking REMICADE<sup>®</sup>?

The following serious (sometimes fatal) side effects have been reported in people taking REMICADE®.

You should tell your doctor right away if you have any of the signs listed below:

- Infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu, or warm, red or painful skin or any open sores. REMICADE® can make you more likely to get an infection or make any infection that you have worse.
- Lymphoma, or any other cancers in adults and children.
- Skin cancer—any changes in or growths on your skin.
- Heart failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- Liver injury—jaundice (yellow skin and eyes), dark brown urine, right-sided abdominal pain, fever, or severe tiredness.
- Blood disorders—fever that doesn't go away, bruising, bleeding or severe paleness.
- Nervous system disorders—numbness, weakness, tingling, changes in your vision or seizures.
- Allergic reactions during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- Lupus-like syndrome—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

The more common side effects with REMICADE® are respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.

Please read the Medication Guide for REMICADE® and discuss it with your doctor. (Requires Adobe® Acrobat® Reader®. Click here to download.)

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.

#### **About Janssen Pharmaceutical Companies**

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We

collaborate with the world for the health of everyone in it. Learn more at <a href="www.janssen.com">www.janssen.com</a>. Follow us on Twitter at <a href="www.twitter.com/JanssenUS">www.twitter.com/JanssenUS</a>.

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## **References**

1. Crohn's & Colitis Foundation of America. What are Crohn's & Colitis? Available at <a href="http://www.ccfa.org/what-are-crohns-and-colitis/">http://www.ccfa.org/what-are-crohns-and-colitis/</a>. Accessed April 6, 2016.