PRESS RELEASE

Media Contact
Caroline Pavis
Mobile: 610-357-3121
CPavis@ITS.JNJ.com

Media Contact
Brian Kenney
Office: 215-628-7010
Mobile: 215- 620-0111
bkenney1@its.jnj.com

Investor Contact
Lesley Fishman
Johnson & Johnson
Office: 732-524-3922

NEW DATA SHOWS STELARA® (USTEKINUMAB) MAINTAINED CLINICAL RESPONSE AND REMISSION AFTER TWO YEARS OF TREATMENT IN ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE

Results of the IM-UNITI Study Presented at the 12th Congress of ECCO

Horsham, Pa., February 17, 2017 – Janssen Biotech, Inc. announced today new two-year data from the ongoing IM-UNITI long-term extension (LTE) study evaluating the efficacy and safety of subcutaneous (SC) STELARA® (ustekinumab) in adult patients with moderately to severely active Crohn's disease. The data presented at the 12th Congress of the European Crohn's and Colitis Organisation (ECCO) showed that treatment with ustekinumab maintained clinical response and remission for up to two years with no new safety signals observed.[1]

"Maintaining control of disease symptoms is paramount in the treatment of Crohn's disease. The two-year clinical response and remission rates from the IM-UNITI study provide further evidence that ustekinumab can be an effective therapeutic option for people living with this chronic and often debilitating disease," said William J. Sandborn, MD, Chief, Division of Gastroenterology, and Professor of Medicine, UC San Diego School of Medicine.

Of the 1,281 patients enrolled in the maintenance study, 397 patients who achieved a response to ustekinumab at week 8 following an induction phase were randomized to receive SC ustekinumab 90mg every 8 weeks (Q8W) or every 12 weeks (Q12W), or placebo during a maintenance (0–44 week) period, before entering the LTE (44–252 week) period. A one-time dose adjustment to ustekinumab 90mg Q8W was permitted in patients in the randomized group who met loss of response criteria between weeks 8–32. Clinical efficacy data were collected every 12 weeks and safety data were collected every 4 weeks from the end of the maintenance trial (week 44) until the maintenance study was unblinded and then at Q8W or Q12W dosing visits during the LTE period; data at week 92 are reported here.

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Among randomized patients who entered the LTE period and continued to receive ustekinumab through week 96, 79.2% (61/77) of patients receiving ustekinumab Q12W and 87.1% (61/70) of patients receiving ustekinumab Q8W were in remission, while 90.9% (70/77) of patients and 94.3% (66/70) of patients showed clinical response at week 92, respectively. Among all ustekinumab-treated patients who continued to receive ustekinumab through week 96, remission and response rates at week 92 were 70.7% (365/516) and 84.7% (437/516), respectively (as observed).

Safety events (per hundred subject years of follow up) were similar in ustekinukab treated patients compared to placebo treated patients from week 44 through to week 96 and were similar in number to event reported in the blinded period of the maintenance trial. Among all ustekinumab-treated patients, there were two deaths (sudden death, asphyxia). There were two non-NMSC (non-melanoma skin cancer) malignancies reported between weeks 44 and 96, a seminoma in an ustekinumab-treated patient and a papillary thyroid cancer in a placebo only treated patient.[1]

“The 96 week data from the IM-UNITI study complement data previously presented from the UNITI program. We look forward to sharing future results from the UNITI program, and remain committed to improving overall outcomes for people living with Crohn’s disease, “said Frederic Lavie, EMEA Therapeutic Area Leader Immunology, Cardiovascular and Metabolics, Janssen Biotech, Inc.

About Crohn’s disease

More than five million people worldwide are living with Crohn’s disease and ulcerative colitis – collectively known as inflammatory bowel disease (IBD).[2] Specifically in the U.S., Crohn’s disease affects as many as 780,000 Americans.[3] The cause of Crohn’s disease is not known, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition or diet and other environmental factors. Symptoms of Crohn’s disease can vary but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss and fever. There is currently no cure for Crohn’s disease.[3,4]

About the IM-UNITI Trial

IM-UNITI, a Phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel group study, evaluated the efficacy and safety of ustekinumab maintenance therapy in adult patients with moderately to severely active Crohn’s disease. Patients who had responded to a single intravenous dose of ustekinumab in the UNITI-1 OR UNITI-2 induction studies were randomized equally to receive maintenance SC ustekinumab 90MG Q8W or Q12W, or placebo. The primary endpoint was clinical remission at week 44, defined by Crohn’s Disease Activity Index (CDAI) scores less than 150 points. Major secondary endpoints at week 44 included clinical response, measured by the proportion of patients who achieved at least a 100-point reduction from baseline CDAI scores, corticosteroid-free clinical remission, clinical remission among patients in remission at the start of the IM-UNITI study, and clinical remission in the subgroup of patients refractory or intolerant to treatment with one or more anti-TNF-alpha therapies. After week 44, all participants who continued to do well were eligible to continue to receive study agent in the second part of the study, a long term extension where the study agent continues to be administered up to week 252.

About STELARA® (ustekinumab)

STELARA® is a prescription medicine used to treat adults 18 years and older with moderately to severely active Crohn’s disease who have already taken other medicine that did not work well enough or they could not tolerate it.

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The recommended treatment regimen for STELARA® is a single intravenous (IV) infusion of the amount of medication based on your body weight administered by a medical professional at week 0, followed by a 90-mg injection given under the skin as directed by your doctor at week 8 and then every 8 weeks thereafter. The injection is administered by a healthcare provider or self-injected only after proper training.

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 your 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 who has 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.

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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 such as: feeling faint, swelling of your face, eyelids, tongue, or throat, 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. Talk to your doctor about the best way to feed your baby if you take 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 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® 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.

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Please 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.

About the 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 www.janssen.com. Follow us on Twitter at https://twitter.com/JanssenGlobal.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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 Biotech, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for products; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent 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. Neither Janssen Biotech, Inc. 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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References

1. Sandborn W, Rutgeerts P, Gasink C *et al.* Long term efficacy and safety of ustekinumab for Crohn's disease: Results from IM-UNITI Long-Term Extension through 2 years. Annual Congress of the European Crohn's and Colitis Organisation (ECCO 2017); 15-18 February, 2017; Barcelona, Spain; Abstract A-1285.
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