News Release

Media Contact:
Kellie McLaughlin
(609) 468-8356 (mobile)

Investor Contacts:
Chris DelOrefice
(732) 524-2955 (office)

Lesley Fishman
(731) 524-3922 (office)

NEW PHASE 2 DATA SHOW STELARA® (USTEKINUMAB) SUSTAINED IMPROVEMENT IN DISEASE ACTIVITY IN ADULTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS THROUGH ONE YEAR

Janssen presents one-year data from continued Phase 2 lupus study during plenary session at ACR/ARHP 2018 Annual Meeting

CHICAGO, October 23, 2018 — The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the continuation of a randomized, placebo-controlled Phase 2 study investigating STELARA® (ustekinumab) in the treatment of active systemic lupus erythematosus (SLE or lupus). The data show sustained improvements across global and organ-specific disease activity measures in patients receiving STELARA continuously through one year and improvements in patients who crossed over from placebo to STELARA at week 24 through one year. The data are being presented at a Plenary Session during the American College of Rheumatology and Association of Rheumatology Health Professionals (ACR/ARHP) 2018 Annual Meeting taking place October 19-24.

"Lupus, a chronic autoimmune disease, can affect the joints, skin, heart, lungs, kidneys and brain. For those who live with it, it can be debilitating and even life-threatening," said Ronald van Vollenhoven, M.D. Ph.D., Director of the Amsterdam Rheumatology and Immunology Center ARC and Professor of Rheumatology, University of Amsterdam and Free University and lead study investigator*. "The positive results of this longer-term Phase 2 study further support the role that IL-12 and -23 cytokines may play in the

pathophysiology of the disease and underscore the need for additional treatment options for patients living with lupus."

The one-year results build on initial data from the Phase 2 trial, which found a significantly higher proportion of patients receiving STELARA showed improvements in lupus disease activity, as measured by the SLE Responder Index (SRI)-4 response, at week 24, compared with placebo (62 percent vs. 33 percent respectively, *P*=0.0057). These findings were presented at the ACR/ARHP 2017 Annual Meeting and were recently published online (September) and in the October print issue of *The Lancet*.

After the 24-week placebo-controlled period of the study, patients receiving placebo crossed over to receive STELARA (90mg SC every 8 weeks), while patients receiving STELARA continued to receive STELARA at the same dose (90mg SC every 8 weeks). Following 48 weeks (or approximately one year) of treatment, data showed the following:

- Of patients initially randomized to STELARA:
    - 63 percent of patients met SRI-4 response criteria.
    - Rates of changes from baseline in SLE Disease Activity-2K (SLEDAI-2K) were sustained from week 24 (65 percent) through one year (67 percent).
    - Rates of Physician Global Assessment (PGA) and active joint responses were sustained from week 24 to one year.
    - Response rate of Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) increased from week 24 (53 percent) through one year (69 percent).
- Of placebo-controlled patients who crossed over to STELARA at week 24, 55 percent achieved an increased SRI-4 response at one year.

Safety was assessed through week 56. Through week 24, similar proportions of adverse events (AEs) across STELARA and placebo treatment groups were reported. Of patients who continued on STELARA or crossed over from placebo to STELARA, 15 percent had serious adverse events (SAE) and 7.5 percent had serious infections through week 56. No deaths, malignancies, opportunistic infections or tuberculosis cases were observed. Safety events were consistent with the known STELARA safety profile.

"Our commitment to innovating on behalf of people with chronic immune diseases is 20 years strong and remains steadfast as we expand our work to help more people in need, including those with lupus," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "These latest findings bring momentum to our research and serve as a catalyst as we advance the program into Phase 3."

Based on the results of the Phase 2 study, Janssen has initiated the Phase 3 LOTUS study. Janssen will collaborate with the Lupus Foundation of America (LFA) to incorporate the Rapid Evaluation of Activity in Lupus (LFA-REAL™) instrument into the

Phase 3 study. LFA-REAL was developed by the LFA as a disease monitoring tool for use in clinical trials and clinical practice. An important feature of the LFA-REAL is that it integrates both clinician and patient input to determine the impact of SLE on the health and daily life of patients. Additionally, Janssen will work with the Lupus Research Alliance (LRA) and its network of leading lupus experts within the Lupus Clinical Investigators Network (LuCIN), to provide a coordinated framework to accelerate the development of STELARA for the treatment of lupus.

"With such a limited amount of treatment options available for patients with lupus, there is a great need for those living with the disease to have the possibility of additional therapies," said Kenneth Farber, President and Chief Executive Officer at Lupus Research Alliance. "We look forward to continuing collaborations with Janssen in the Phase 3 study to further evaluate STELARA as a potential treatment option."

About the Phase 2 STELARA SLE Trial

The efficacy and safety of STELARA was evaluated in a global Phase 2, randomized, placebo-controlled trial in 102 adults with seropositive SLE by Systemic Lupus International Collaborating Clinics (SLICC) criteria and active disease despite ongoing standard of care therapy (steroid, antimalarial and/or immunosuppressive therapies). Patients were randomized (3:2) to receive intravenous (IV) STELARA 6 mg/kg or placebo (PBO) at week 0, followed by subcutaneous (SC) injections of STELARA 90 mg or placebo every eight weeks, both in addition to standard of care therapy for 24 weeks. At week 24, patients in the placebo arm crossed over to active study agent. Modified intention-to-treat (mITT) analyses across SLE disease activity measures were performed to evaluate maintenance of response with STELARA between week 24 and week 48. Safety was assessed through week 56.

The primary endpoint was the proportion of patients achieving SRI-4 response at week 24. The SRI combines scores from three different validated lupus disease indexes to define responders versus non-responders, and has previously been accepted by health authorities in SLE registration trials. To achieve SRI-4 response, an individual with lupus must have at least a four-point improvement on the SLEDAI-2K score, less than 10 percent increase in PGA of disease activity and no worsening of moderate/severe organ disease on the British Isles Lupus Assessment Group (BILAG) disease activity index. Major secondary endpoints included change from baseline in SLEDAI-2K score, change from baseline in PGA of disease activity, and proportion of patients with BILAG-Based Composite Lupus Assessment (BICLA) response, all at week 24. Joint and cutaneous disease activity were also assessed with joint counts and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI), respectively.

Endpoint analyses included all patients who received at least one dose of study agent, had at least one measurement prior to administration, and had at least one post-baseline measurement. Patients with missing data and treatment failures were imputed

as non-responders. Long-term safety and efficacy data are currently being collected through 104 weeks.

About SLE

Lupus is a chronic, inflammatory autoimmune disorder that can affect many different body systems, including joints, skin, heart, lungs, kidneys and brain.[1] SLE, the most common form of lupus, can range from mild to severe and is characterized by inflammation of any organ system including kidneys, nervous system, brain or brain vasculature, as well as potential hardening of the arteries or coronary artery disease.[2] The disease most often affects women and disproportionately affects women of African American, Hispanic, Asian and Native American descent compared to Caucasian women.[3] Lupus is estimated to affect at least 1.5 million Americans and 5 million people worldwide.[4]

About STELARA®

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 and can be 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® 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
- 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 or call 1-800-FDA-1088.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

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 http://www.janssen.com/. Follow us at http://www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding new study data on STELARA. 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, any of the other Janssen Pharmaceutical Companies 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, 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 the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

**Dr. van Vollenhoven is a paid consultant for Janssen. He was not compensated for any media work.*

# # #

1. Mayo Clinic. Lupus. Available at: http://www.mayoclinic.org/diseases-conditions/lupus/basics/definition/con-20019676. Accessed September 14, 2018.
2. Lupus Foundation of America. Different Types of Lupus. Available at https://resources.lupus.org/entry/types-of-lupus. Accessed September 14, 2018.
3. Lupus Research Alliance. About Lupus. Available at http://www.lupusresearch.org/understanding-lupus/what-is-lupus/about-lupus/. Accessed September 14, 2018.
4. Lupus Foundation of America. What is Lupus? Available at https://resources.lupus.org/entry/what-is-lupus?utm_source=lupusorg&utm_medium=answersFAQ. Accessed September 14, 2018.