NEWS RELEASE

Media Contacts:
Megan Farina
610-724-1079
mfarina@its.jnj.com

Brian Kenney
215-620-0111
bkenney1@its.jnj.com

Investor Contacts:
Lesley Fishman
732-524-3922
lfishma@its.jnj.com

Joseph J. Wolk
732-524-1142
jwolk2@its.jnj.com

JANSSEN ANNOUNCES U.S. FDA APPROVAL OF TREMFYA™ (GUSELKUMAB) FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

- *TREMFYA™ is the first and only biologic approved that selectively blocks interleukin (IL)-23.*
- *Seven out of ten patients receiving TREMFYA™ achieved at least 90 percent improvement in skin clearance at week 16.*
- *Nearly three quarters of TREMFYA™-treated patients demonstrated at least 90 percent clearer skin at week 48.*
- *TREMFYA™ demonstrated superior results in skin clearance compared with Humira®* (adalimumab) in head-to-head analyses at weeks 16, 24 and 48.*

Horsham, PA, July 13, 2017 — Janssen Biotech, Inc. (Janssen) announced today that the U.S. Food and Drug Administration (FDA) has approved TREMFYA™ (guselkumab) for the treatment of adults living with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. TREMFYA™ is the first and only approved biologic therapy that selectively blocks only IL-23, a cytokine that plays a key role in plaque psoriasis. Approval comes after an expedited regulatory review following application of an FDA Priority Review Voucher. TREMFYA™ is administered as a 100 mg subcutaneous injection every eight weeks, following two starter doses at weeks 0 and 4. In clinical studies, patients receiving TREMFYA™ experienced significant improvement in skin clearance and greater improvement in symptoms of plaque psoriasis including itch, pain, stinging, burning and skin tightness when compared with placebo at week 16. Superior results in skin clearance (PASI 90) were demonstrated with TREMFYA™ compared with Humira® (adalimumab) at weeks 16, 24 and 48.

“TREMFYA™ represents a significant milestone in the treatment of moderate to severe plaque psoriasis as evidenced by the proven skin clearance demonstrated in the majority of study patients receiving this IL-23–specific therapy at week 16 and up to week 48,” said Andrew Blauvelt, M.D., M.B.A., President of Oregon Medical Research Center, and study investigator. “We continue to make progress in understanding the science of psoriasis and the important role IL-23 plays in the pathogenesis of this disease, which is another reason why today’s approval of TREMFYA™ is exciting, both as a researcher and a practicing dermatologist.”

“Living with plaque psoriasis is challenging, especially the constant pain, itching and burning,” said Patti Janick, a guselkumab clinical trial participant. “I am encouraged by the results I’ve experienced with TREMFYA™ and the possibility it offers others living with plaque psoriasis to find similar relief and clearer skin.”

TREMFYA™ received FDA approval based on results from a clinical development program that included more than 2,000 patients in the Phase 3 VOYAGE 1, VOYAGE 2 and NAVIGATE studies, which have been published in peer-reviewed journals and were presented at the 25th European Academy of Dermatology and Venerology Congress and the 2017 American Academy of Dermatology Annual Meeting.

- Results from VOYAGE 1 and VOYAGE 2 demonstrated significant efficacy in patients with moderate to severe plaque psoriasis treated with TREMFYA™.
- In clinical studies, at 16 weeks, at least seven out of ten TREMFYA™-treated patients achieved at least 90 percent clearer skin, and more than 80 percent demonstrated cleared or almost cleared skin.
- Improvements were also demonstrated with TREMFYA™ in psoriasis involving the scalp and in symptoms of plaque psoriasis including itch, pain, stinging, burning and skin tightness at week 16.
- Treatment with TREMFYA™ resulted in clearer skin that lasted, as nearly nine out of ten TREMFYA™-treated patients who achieved PASI 90 at week 28 maintained that response at week 48.
- Versus Humira®, at week 24, more than seven out of ten patients treated with TREMFYA™ reported at least 90 percent clearer skin compared with more than four out of ten patients treated with Humira®.
- NAVIGATE findings demonstrated the effectiveness of TREMFYA™ in patients who had an inadequate response to treatment with STELARA® (ustekinumab). At week 28, 31 percent of TREMFYA™-treated patients were considered cleared or almost cleared versus 14 percent of STELARA®-treated patients 12 weeks after randomization to continue STELARA® or transition to TREMFYA™.

“Addressing the need for additional safe and effective plaque psoriasis therapies has been a critical area of focus at Janssen for more than 15 years,” said Andrew Greenspan, M.D., Vice President of Medical Affairs at Janssen. “Considering this, we applied a priority review voucher to the application for TREMFYA™ to bring this novel treatment to patients sooner.”

“The approval of new and effective treatment options is always welcome news for the plaque psoriasis patient community, as not all patients respond similarly to currently available treatments,” said Michael Siegel, Ph.D., Vice President of Research Programs for the National Psoriasis Foundation. “For the more than one million Americans living with moderate to severe plaque psoriasis, the approval of TREMFYA™ is a meaningful addition and offers physicians and patients an effective new, first-in-class therapy that selectively inhibits IL-23.”

Janssen will work closely with payers, providers and pharmacy benefit managers to ensure TREMFYA™ is broadly accessible and affordable for patients and that the cost for payers is competitive with currently available biologic therapies for psoriasis. Janssen offers a number of patient support programs, including a co-pay card for patients with commercial insurance that reduces their out-of-pocket cost for TREMFYA™ to no more than $5 per dose.

Full Prescribing Information and Medication Guide will be available soon at www.tremfyahcp.com.

Efficacy Evaluation

The TREMFYA™ versus placebo analysis is based on the results of an analysis of 101 global sites from VOYAGE 1 and 115 global sites from VOYAGE 2 (including North American sites [i.e., U.S. and Canada]).

*The TREMFYA™ versus Humira® analysis is based on the results of an analysis of 38 North American sites (U.S.=27, Canada=11) from VOYAGE 1 and 41 North American sites (U.S.=31, Canada=10) from VOYAGE 2 that utilized U.S.-licensed Humira®.

About TREMFYA™ (guselkumab)

TREMFYA™ is a human monoclonal antibody developed by Janssen that selectively blocks the protein interleukin (IL)-23 and is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light). A Phase 3 study evaluating TREMFYA™ in the treatment of active psoriatic arthritis is ongoing, and a Phase 3 program evaluating the efficacy of TREMFYA™ compared with Cosentyx® (secukinumab) in the treatment of moderate to severe plaque psoriasis is underway.

Applications seeking approval in the European Union, Japan and other countries are currently under review.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA™?

TREMFYA™ may cause serious side effects, including infections. TREMFYA™ is a prescription medicine that 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

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.
- 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: upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, and herpes simplex infections.

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.

075142-170622

About STELARA® (ustekinumab)
STELARA® is a human interleukin (IL)-12 and IL-23 antagonist indicated in the U.S. for the treatment of adult patients with: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; active psoriatic arthritis, alone or in combination with methotrexate; and moderately to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids but never failed treatment with a tumor necrosis factor (TNF) blocker, or who failed or were intolerant to treatment with one or more TNF blockers.

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 89 countries, active psoriatic arthritis in 79 countries, pediatric psoriasis in 33 countries and moderately to severely active Crohn's disease in 32 countries.

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.

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.

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 Psoriasis

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain.[1] It is estimated that more than 7.5 million Americans live with the disease.[2] Approximately 80 percent of those affected with psoriasis have mild to moderate disease, while 20 percent have moderate to severe plaque psoriasis.[2]

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/JanssenUS or 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 potential benefits and continued development of TREMFYA™ (guselkumab). 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 the uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products or new indications; 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 January 1, 2017, including under “Item 1A. Risk Factors,” its most recently filed Quarterly Report on Form 10-Q, including in the section captioned “Cautionary Note Regarding Forward-Looking Statements,” 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.

###

References

1. National Psoriasis Foundation. About Psoriasis. https://www.psoriasis.org/about-psoriasis. Accessed June 20, 2017.
2. American Academy of Dermatology. Psoriasis. https://www.aad.org/media/stats/conditions/psoriasis Accessed June 20, 2017.