News Release

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Janssen Highlights Latest Research for TREMFYA® (guselkumab) and Investigational Targeted Oral Peptide JNJ-2113 in Moderate to Severe Plaque Psoriasis at the European Academy of Dermatology and Venereology (EADV) Congress

30 presentations showcase breadth of data from Janssen's Immunodermatology pipeline across five commercialized and investigational therapies

SPRING HOUSE, PENNSYLVANIA, October 9, 2023 – Janssen Pharmaceuticals, Inc., a Johnson & Johnson company, today announced that 30 company-sponsored presentations will be featured at the European Academy of Dermatology and Venereology (EADV) Congress taking place in Berlin, Germany from October 11-14, 2023. Janssen will present new data on the underlying science of the treatment of psoriasis (PsO), including results from the Phase 3b GUIDE trial highlighting early intervention with TREMFYA® (guselkumab) (Abstract #FC08.5)[1] and systemic pharmacodynamic[a] response data for JNJ-2113 from the Phase 2 FRONTIER 1 trial (Abstract #FC08.2).[2]

In the GUIDE trial, the results experienced by super responders[b] with short disease duration of PsO who were treated with TREMFYA extended beyond high levels of Psoriasis Area and Severity Index (PASI) responses.[c] These results support the potential for tailored therapeutic strategies, which could address individual patient needs, reinforcing the data on early intervention with TREMFYA.[1]

In addition, new FRONTIER 1 data show for the first time that the targeted oral peptide JNJ-2113 induces a strong systemic pharmacodynamic response versus placebo in people living with moderate to severe plaque PsO.[2] Investigational JNJ-2113 is the first and only targeted oral peptide designed to block the IL-23 receptor, which underpins the inflammatory response in PsO and other IL-23-mediated diseases.[2]

"The breadth of data we are presenting at EADV underscores our commitment to developing new treatments for people living with moderate to severe plaque psoriasis, a disease that can cause significant physical and emotional burden," said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Stronghold Leader, Janssen Research & Development, LLC. "Patients are waiting for a new option with the goal of helping manage their plaque psoriasis symptoms, which could potentially transform the treatment paradigm. The data from these presentations add to the comprehensive body of scientific evidence for our investigational and established therapies, potentially offering people living with moderate to severe plaque psoriasis much-needed relief from their symptoms."

A selection of Janssen-sponsored abstracts being featured at EADV is provided below.

Abstract Number	**Title**	**Presentation Time (CEST)**
FC08.5	Treatment-Free Period of More Than 1 Year in Guselkumab Super Responders with Short Disease Duration of Psoriasis: Withdrawal Data from the GUIDE Trial	October 13 at 4:40 p.m.

FC08.9	A Phase 2, Randomized, Placebo-Controlled, Dose-Ranging Study of Oral JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis: Efficacy of Overall and Scalp Psoriasis Responses from FRONTIER 1	October 13 at 5:20 p.m.
FC08.2	JNJ-77242113 Treatment Induces a Strong Systemic Pharmacodynamic Response Versus Placebo in Serum Samples of Patients with Plaque Psoriasis: Results from the Phase 2, FRONTIER 1 Study	October 13 at 4:10 p.m.
P0713	Guselkumab, an IL-23p19 Subunit–Specific Monoclonal Antibody, Is Able to Bind CD64+ Myeloid Cells, Potently Neutralise IL-23 Produced from the Same Cells, and Mediate Internalisation of IL-23 by CD64+ Macrophages	E-Poster
P2333	Consistent Skin Clearance with Guselkumab Treatment for Up to 5 Years in Patients with Moderate to Severe Psoriasis Irrespective of Baseline Disease Extent or Severity in the VOYAGE 1 and 2 Studies	E-Poster
P2339	Effectiveness and Safety of Guselkumab in Patients with Moderate to Severe Psoriasis and Facial and/or Genital Involvement: Interim Analysis of Results Up to Week 28 from the GULLIVER Study	E-Poster
P2325	Influence of Guselkumab Therapy on Libido in Patients with Moderate to Severe Psoriasis in Clinical Routine: Interim Analysis of the Non-Interventional German G-EPOSS Study After 28 Weeks	E-Poster
P2551	Use of Patient Reported Outcomes (PROMs) Information in Clinical Practice in Spain for Clinical Management of Psoriasis Patients – SUMMER Project	E-Poster
P0752	Impact of Guselkumab in Real Life on Different Quality of Life Outcomes in Patients with Moderate to Severe Psoriasis: CASSIOPEE Study	E-Poster

Additional featured abstracts further highlight the long-term data of TREMFYA in adults with moderate to severe plaque PsO. Janssen-sponsored abstracts can also be found on the EADV website.

Editor's Notes:

a. Systemic pharmacodynamics is the study of the biochemical and physiologic effects of drugs in the body.
b. Super responders are defined as people achieving PASI=0 (clear skin) at weeks 20 and 28 of treatment with guselkumab in the GUIDE study.[1]
c. The PASI score grades the amount of surface area covered by PsO plaques at each body region and the severity of plaques based on their degree of redness, thickness and scaling.[3]

About Plaque Psoriasis (PsO)

Plaque PsO is an immune-mediated disease resulting in overproduction of skin cells,

which causes inflamed, scaly plaques that may be itchy or painful.[4] It is estimated that eight million Americans and more than 125 million people worldwide live with the disease.[5] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate to severe.[5] Living with plaque PsO can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[6]

About TREMFYA® (guselkumab)

Developed by Janssen, TREMFYA is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.[7,8] IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque PsO and active PsA.[8] TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque PsO who are candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.[7,9,10] It is also approved in the EU for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior conventional synthetic disease modifying antirheumatic drug therapy.[3]

In vitro studies have demonstrated that TREMFYA binds to CD64 expressed on the surface of IL-23 producing cells and captures IL-23 produced from these same cells when bound to CD64 in a monocyte cell culture model.[11,12,13,14] The clinical significance of this finding is not known.[15]

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

About JNJ-2113

JNJ-2113 (formerly PN-235) was discovered and is being developed pursuant to the license and collaboration agreement between Protagonist Therapeutics and Janssen Biotech, Inc. Janssen retains exclusive worldwide rights to develop JNJ-2113 in Phase 2 clinical trials and beyond, and to commercialize compounds derived from the research conducted pursuant to the agreement for a broad range of indications.[16]

Investigational JNJ-2113 is the first targeted oral peptide designed to block the IL-23 receptor, which underpins the inflammatory response in PsO and other IL-23-mediated diseases. JNJ-2113 binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, selective inhibition of IL-23 signaling in human T cells.[17] The license and collaboration agreement established between Protagonist and Janssen Biotech, Inc. in 2017 enabled the companies to work together to discover and develop next-generation compounds that ultimately led to JNJ-2113.[18,19]

IMPORTANT SAFETY INFORMATION

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

TREMFYA® is a prescription medicine that may cause serious side effects, including:

- **Serious Allergic Reactions.** Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
    - fainting, dizziness, feeling lightheaded (low blood pressure)
    - swelling of your face, eyelids, lips, mouth, tongue or throat
    - trouble breathing or throat tightness
    - chest tightness
    - skin rash, hives
    - itching

- **Infections.** TREMFYA® 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

Do not take TREMFYA® if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

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, herpes simplex infections, and bronchitis.

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.
cp-82626v3

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JNJInnovMed and @JanssenUS.

Janssen Research & Development, LLC; Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC are 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 TREMFYA and JNJ-2113. 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, Janssen Biotech, Inc., Janssen Scientific Affairs, LLC s 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 January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements"

and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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. None of Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Scientific Affairs, LLC 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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