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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 commercialised and investigational therapies

BEERSE, BELGIUM, 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 11-14 October, 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 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 guselkumab 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 guselkumab.[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	13 October 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	13 October 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	13 October 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 guselkumab 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 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, guselkumab 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] Guselkumab is approved in the EU for the treatment of moderate to severe plaque Pso in adults who are candidates for systemic therapy, and alone or in combination with methotrexate for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[8] It is also 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]

In vitro studies have demonstrated that guselkumab 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 commercialise 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 signalling 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]

GUSELKUMAB IMPORTANT SAFETY INFORMATION

In controlled periods of clinical studies with guselkumab, adverse drug reactions (ADRs) that consisted of respiratory tract infections were very common (≥10 percent); increased transaminases, headache, diarrhoea, arthralgia, and injection site reactions were common (≥1 to <10 percent); and herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash were uncommon ADRs (≥0.1 percent to <1 percent).[8]

Please refer to the Summary of Product Characteristics for full prescribing information for guselkumab in Pso and PsA: https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf

ADRs should be reported. Reporting forms and information can be found at

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. ADRs should also be reported to Janssen-Cilag Ltd. on +44 (0) 1494567447.

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/emea. Follow us at www.twitter.com/JanssenEMEA.

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 guselkumab 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 materialise, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Scientific Affairs, LLC 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 behaviour 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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