Johnson&Johnson

Media contact:
Craig Stoltz
Mobile: (215) 779-9396
cstoltz@its.jnj.com

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

For immediate release

New data shows JNJ-2113, the first and only investigational targeted oral peptide, maintained skin clearance in moderate-to-severe plaque psoriasis through one year

JNJ-2113 long-term extension FRONTIER 2 study demonstrated sustained efficacy from Week 16 to Week 52 and safety results consistent with previously reported data (FRONTIER 1 Study) in a late-breaking oral presentation at the American Academy of Dermatology 2024 Annual Meeting

SAN DIEGO (March 9, 2024) – Johnson & Johnson today announced the first data from FRONTIER 2, the long-term extension of the Phase 2b FRONTIER 1 clinical trial evaluating JNJ-2113, the first and only investigational targeted oral peptide designed to block the IL-23 receptor (Abstract #S026).[1,2] IL-23 plays a critical role in pathogenic T-cell activation in moderate-to-severe plaque psoriasis (PsO) and underpins the inflammatory response in PsO and other dermatological, rheumatological and gastroenterological IL-23-mediated diseases.[3,4]

In FRONTIER 2, JNJ-2113 maintained high rates of skin clearance through 52 weeks in adults with moderate-to-severe plaque PsO.[1] In the five JNJ-2113 treatment groups, as measured by the Psoriasis Area and Severity Index (PASI)[a], response rates were maintained from Week 16 to Week 52, with the highest PASI 75 response observed in the 100 mg twice daily group (78.6 at 16 weeks and 76.2 percent at 52 weeks).[1,b] Similar to the primary endpoint, responses were maintained through Week 52 for all five JNJ-2113 treatment groups for the key secondary endpoints of PASI 90 (59.5 at 16 weeks and 64.3 percent at 52 weeks), PASI 100 (40.5 percent at 16 weeks and 40.5 percent at 52 weeks), Investigator's Global Assessment (IGA)[c] 0/1 (64.3 percent at 16 weeks and 73.8 percent at 52 weeks) and IGA 0 (45.2 percent at 16 weeks and 42.9 percent at 52 weeks).[1]

Safety in the FRONTIER 2 long-term extension study (Week 16 through Week 52) was found to be consistent with FRONTIER 1.[1,2] Across JNJ-2113 treatment groups, 58.6 percent of patients experienced adverse events (AEs), with no evidence of dose-dependent increase in AEs, including gastrointestinal disorders.[1] The most frequently reported AEs were nasopharyngitis (18.1 percent), upper respiratory tract infection (9.7 percent) and COVID-19 (5.3 percent).[1] Serious AEs were uncommon, occurring in 4 percent of the combined JNJ-2113 patients through Week 52, and all serious AEs were considered unrelated to study treatment.[1]

"Data from the FRONTIER 2 study showed that the skin clearance as seen by PASI 75 and higher-bar PASI 90 and 100 responses at 16 weeks was maintained at 52 weeks with no new safety signals across all JNJ-2113 treatment groups," said Laura Ferris, M.D., Ph.D., Professor of Dermatology, University of Pittsburgh.[d] "These findings suggest the potential for JNJ-2113 to continue delivering clinically meaningful results, and addresses the high unmet need for a novel, durable, and convenient oral therapeutic option for people living with moderate-to-severe plaque psoriasis."

In FRONTIER 2, patients who originally received JNJ-2113 in FRONTIER 1 during the first 16 weeks continued with the same dosing regimen they received in the earlier part of the trial.[1] Patients who were originally in the placebo group received JNJ-2113 100 mg once daily in FRONTIER 2.[1] Data from the Phase 2b FRONTIER 1 study evaluating JNJ-2113 in adults with moderate-to-severe PsO were recently published in *The New England Journal of Medicine*.[5]

The pivotal Phase 3 ICONIC clinical development program is currently underway to evaluate the safety and efficacy of JNJ-2113 in adults with moderate-to-severe plaque PsO, including the ICONIC-LEAD[e] and ICONIC-TOTAL[f] studies – pursuant to the license and collaboration agreement between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc.[6] Other Phase 3 studies in the development program have

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investor-relations@its.jnj.com

been initiated, including ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2, which will evaluate the safety and efficacy of JNJ-2113 compared with both placebo and deucravacitinib.[7]

The findings from the FRONTIER 1 and FRONTIER 2 clinical trials suggest the potential of JNJ-2113 across the spectrum of additional IL-23-mediated diseases.[1,8] Accordingly, J&J has initiated the Phase 2b ANTHEM-UC study to evaluate the safety and effectiveness of JNJ-2113 compared with placebo in participants with moderately to severely active ulcerative colitis.[8]

"Our strong commitment to innovation in Immunodermatology advances our overall mission to bring new treatment options to market to achieve remission in patients with immune-mediated conditions," said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Johnson & Johnson. "With promising longer-term results showcasing one year of JNJ-2113 data from the FRONTIER 2 study, our focused innovation in the IL-23 pathway provides an exciting opportunity to unlock a new and potentially differentiated treatment option for patients with psoriasis."

Editor's Notes:

a. The PASI score grades the amount of surface area on each body region that is covered by PsO plaques and the severity of plaque redness, thickness, and scaliness.[9]

b. There were no formal statistical comparisons, as the placebo arm transitioned to JNJ-2113 100 mg daily dose at Week 16.[1]

c. The IGA is a five-point scale with a severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate, and 4 indicates severe disease.[5]

d. Dr. Laura Ferris is a paid consultant for Johnson & Johnson. She has not been compensated for any media work.

e. ICONIC-LEAD is a randomized controlled trial (RCT) to evaluate the safety and efficacy of JNJ-2113 compared with placebo in participants with moderate-to-severe plaque PsO, with the higher efficacy bar of PASI 90 and IGA score of 0 or 1 with at least a 2-grade improvement as co-primary endpoints.[10]

f. ICONIC-TOTAL is a RCT to evaluate the efficacy and safety of JNJ-2113 compared with placebo for the treatment of PsO in participants with at least moderate severity affecting special areas (e.g., scalp, genital, and/or palms of the hands and the soles of the feet) with overall IGA score of 0 or 1 with at least a 2-grade improvement as the primary endpoint.[11]

About FRONTIER 2

FRONTIER 2 (NCT05364554) is a Phase 2b multicenter, double-blind, long-term extension, dose-ranging study to evaluate the efficacy and safety of JNJ-77242113 (JNJ-2113) for the treatment of moderate-to-severe plaque psoriasis.[12] The study evaluated four once-daily and two twice-daily dosages of JNJ-2113 taken orally.[12] The originating study (FRONTIER 1) began with its first participant screened on February 3, 2022.[13] A total of 337 participants were screened of which 255 participants were randomized into six treatment groups (Placebo (n=43), 25 mg daily (n=43), 50 mg daily (n=43), 25 mg twice daily (n=41), 100 mg daily (n=43), 100mg twice daily (n=43)).[12] At Week 16, a total of 227 participants from FRONTIER 1 entered FRONTIER 2 long-term extension study and received at least one dose of study intervention (Placebo → 100 mg daily (n=35), 25 mg daily (n=35), 50 mg daily (n=39), 25 mg twice daily (n=40), 100 mg daily (n=40), 100 mg twice daily (n=38)).[12] The first participant in FRONTIER 2 study was dosed on June 10, 2023.[12] A total of 227 participants were randomized into six treatment groups. The total duration of the trial was 52 weeks.[12]

About Plaque Psoriasis

Media contact:
Craig Stoltz
Mobile: (215) 779-9396
cstoltz@its.jnj.com

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

Plaque psoriasis (PsO) is an immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[14] It is estimated that eight million Americans and more than 125 million people worldwide live with the disease.[15] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate to severe.[15] 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.[16]

About JNJ-77242113 (JNJ-2113)

JNJ-2113 was jointly discovered and is being developed pursuant to the license and collaboration agreement between Protagonist Therapeutics and Johnson & Johnson. Johnson & Johnson 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 against a broad range of indications.[17,18,19]

Investigational JNJ-2113 is the first targeted oral peptide designed to block the IL-23 receptor,[2] which underpins the inflammatory response in moderate-to-severe plaque PsO and other IL-23-mediated diseases.[3,4] 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.[20] 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.[21]

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.
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Janssen Research & Development, LLC and Janssen Biotech, Inc. are both Johnson & Johnson companies.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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. 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, 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

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Research & Development, LLC, 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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