NEWS RELEASE

Janssen Submits Application To FDA Seeking Approval Of Anti-Interleukin-23 Monoclonal Antibody Guselkumab For The Treatment Of Moderate To Severe Plaque Psoriasis

11/17/2016

HORSHAM, Pa., Nov. 17, 2016 /PRNewswire/ -- Janssen Biotech, Inc. (Janssen) announced today the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval of guselkumab for the treatment of adults living with moderate to severe plaque psoriasis. Guselkumab is a human monoclonal antibody that targets interleukin (IL)-23, a protein which has been shown to play a key role in the development of immune-mediated inflammatory diseases. Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterized by raised, inflamed, scaly, red lesions, or plaques, which can cause itching, discomfort and pain. It is estimated that 7.5 million Americans have psoriasis, which can range from mild to severe and disabling.[1]

"We are committed to translating scientific advances into innovative therapies for chronic immune-mediated diseases like plaque psoriasis," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "We look forward to working with the FDA during the agency's review of the application as we believe guselkumab addresses continued needs of patients living with moderate to severe plaque psoriasis."

Data from four studies evaluating the efficacy and safety of guselkumab administered by subcutaneous injection in the treatment of adults living with moderate to severe plaque psoriasis served as the basis for the submission. These studies include VOYAGE 1, VOYAGE 2 and NAVIGATE Phase 3 studies, and the X-PLORE Phase 2 study, which **appeared** in The New England Journal of Medicine in July 2015. Results from the VOYAGE 1 study were recently

presented at the European Academy of Dermatology and Venereology congress, and results from the VOYAGE 2 and NAVIGATE studies are planned for presentation at upcoming scientific congresses.

About Guselkumab

Guselkumab is a human monoclonal antibody with a novel mechanism of action that targets the protein interleukin (IL)-23 and is in Phase 3 development as a subcutaneously administered therapy for the treatment of moderate to severe plaque psoriasis. Additionally, findings from a Phase 2 study evaluating guselkumab in the treatment of patients with active psoriatic arthritis were recently presented at the American College of Rheumatology meeting and a Phase 3 program for this indication is planned.

About Psoriasis

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterized by raised, inflamed, scaly, red lesions, or plaques, which can cause physical pain and itch. It is estimated that as many as 125 million people worldwide have psoriasis, including 7.5 million Americans, and nearly one-quarter of people affected have cases that are considered moderate to severe.[1-7]

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 **www.janssen.com**. Follow us at **Twitter.com/JanssenGlobal**.

Janssen Biotech, Inc. and Janssen Research & Development, 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 new product development. 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., Janssen Research & Development, LLC and 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action; 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 3, 2016, including in Exhibit 99 thereto, 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. None of the Janssen Pharmaceutical Companies or 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. Psoriasis Fact Sheet. **https://www.psoriasis.org/sites/default/files/psoriasis_fact_sheet.pdf**. Accessed September 11, 2016.

2. National Psoriasis Foundation. People of All Races Overcome Psoriatic Disease. **https://www.psoriasis.org/advance/features/people-of-all-races-overcome-the-challenge-of-psoriatic-diseases**. Accessed September 11, 2016.

3. Augustin M, et al. Prevalence of skin lesions and need for treatment in a cohort of 90 880 workers. Br J Dermatol. 2011;165:865-873.

4. Ortonne J, et al. Alefacept: a novel and selective biologic agent for the treatment of chronic plaque psoriasis. Eur J Dermatol. 2004;14:41-45.

5. Parisi R, et al. Global Epidemiology of Psoriasis: A Systematic Review. J Invest Dermatol. 2013;133:377-385.

6. World Population statistics. Population of Europe 2014. **http://www.worldpopulationstatistics.com/population-of-europe-2014**. Accessed September 11, 2016.

7. The Dermatologist. World Psoriasis Day 2013 Puts A Face on the Skin Disease. **http://www.the-dermatologist.com/node/2825**. Accessed November 4, 2016.

Media Contact:
Brian Kenney
Office: 215-628-7010
Mobile: 215-620-0111

Investor Contacts:
Joseph J. Wolk
Johnson & Johnson
Office: 732-524-1142

Lesley Fishman
Johnson & Johnson
Office: 732-524-3922

Logo - **http://photos.prnewswire.com/prnh/20161117/440664LOGO**

To view the original version on PR Newswire, visit:**http://www.prnewswire.com/news-releases/janssen-submits-application-to-fda-seeking-approval-of-anti-interleukin-23-monoclonal-antibody-guselkumab-for-the-treatment-of-moderate-to-severe-plaque-psoriasis-300365063.html**

SOURCE Janssen Biotech, Inc.