News Release

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FDA ADVISORY COMMITTEE DOES NOT RECOMMEND APPROVAL OF SIRUKUMAB FOR THE TREATMENT OF MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS

HORSHAM, PA, August 2, 2017 – Janssen Biotech, Inc. announced today that the Arthritis Advisory Committee of the U.S. Food and Drug Administration (FDA) did not recommend approval of sirukumab (proposed trade name PLIVENSIA™) for the treatment of moderately to severely active rheumatoid arthritis (RA) in adults who have had an inadequate response or are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Sirukumab is an anti-interleukin (IL)-6 monoclonal antibody that blocks the IL-6 pathway differently than IL-6 inhibitors currently approved for the treatment of RA. Janssen Biotech, Inc. announced submission of a Biologics License Application (BLA) to the FDA seeking approval of sirukumab on September 23, 2016.

“We appreciate the advisory committee’s thoughtful review and discussion of the sirukumab efficacy and safety data during today’s meeting. While the committee voted unanimously in support of the efficacy data, there was uncertainty regarding the safety profile. As a result, the committee did not support approval for the proposed indication. We are disappointed and disagree with the group’s interpretation of the sirukumab benefit-to-risk profile,” said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. “We remain confident in the data accumulated to date supporting sirukumab in the treatment of moderately to severely active rheumatoid arthritis. We look to continue discussions with the FDA in their review of the application as we believe sirukumab represents an important therapeutic option for patients with rheumatoid arthritis.”

The Arthritis Advisory Committee is convened upon the request of the FDA to review and evaluate safety and efficacy data of human products for use in the treatment of arthritis. While the FDA is not bound by the committee’s recommendation, it does take its advice into consideration.

The committee reviewed sirukumab efficacy and safety data from a global Phase 3 clinical development program inclusive of five studies and more than 3,000 patients living with RA, including those who continue to have active disease despite previous DMARD and biologic treatments. Sirukumab, studied at 50 mg and 100 mg doses every four and two weeks, respectively, demonstrated significant efficacy in the

treatment of RA, improving signs and symptoms, inhibiting the progression of structural damage and demonstrating improvement in patient-reported outcome measures including fatigue, pain, quality of life and physical function.

The most common adverse events (AEs) reported in the sirukumab clinical development program included laboratory abnormalities, colds, upper respiratory tract infections, and redness, pain or swelling at the injection site. Serious AEs reported included serious infections such as pneumonia and cellulitis, abscess, sepsis, osteomyelitis, hypersensitivity reactions, low platelets, lipid elevations and gastrointestinal perforations. Cardiovascular adverse events, malignancies and mortality were observed in sirukumab clinical studies.

“Rheumatoid arthritis continues to be a disease with a high unmet need for many patients who are intolerant to or lose response over time to currently available treatment options,” said Sergio Schwartzman, M.D., Weill Cornell Medical College, Hospital for Special Surgery, New York Presbyterian Hospital, an external consultant. “The availability of alternative treatment options, including a new molecular entity like sirukumab, is critically important in my ability as a practicing rheumatologist to help patients control their disease, especially considering the complexity and heterogeneity of an autoimmune disease like rheumatoid arthritis. It is my hope that the FDA carefully considers all of the Phase 3 data and the current need for additional rheumatoid arthritis treatment options on behalf of patients and practicing rheumatologists.”

About Sirukumab

Sirukumab is a fully human monoclonal IgG1 kappa antibody that selectively blocks circulating IL-6, a naturally occurring protein that is believed to play a role in autoimmune conditions like RA. It is not yet approved as a treatment for rheumatoid arthritis or for any other indication anywhere in the world. Sirukumab is different from other IL-6 inhibitors currently approved for the treatment of RA as it targets the IL-6 cytokine, whereas other agents target the IL-6 receptor.

Sirukumab is currently being evaluated by health authorities in the U.S., Europe and Japan as a subcutaneous therapy for the treatment of adult patients with moderately to severely active RA.

Janssen currently holds exclusive rights to commercialize sirukumab in Europe, the Middle East, Africa and Asia Pacific, and will regain exclusive, worldwide commercial rights in November 2017 following GSK’s recent decision to terminate its rights under a 2011 agreement that had given it co-development rights and the right to commercialize sirukumab in North, Central and South America.

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic, systemic inflammatory condition that is characterized by pain, joint swelling, stiffness, joint damage/tissue destruction and disability.[1] Approximately 1.5 million people in the U.S. are affected by the condition for which there is no cure.[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/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 development and potential regulatory approval of sirukumab. 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/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; event if approved, the uncertainty of commercial success; 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," it's most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," and in 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.

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References

[1] Centers for Disease Control and Prevention. "Rheumatoid Arthritis (RA)," Available at: http://www.cdc.gov/arthritis/basics/rheumatoid.htm. Accessed June 30, 2017.
[2] Arthritis Foundation. "What is Rheumatoid Arthritis." Available at: http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/what-is-rheumatoid-arthritis.php. Accessed August 2, 2017.