Press Release

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JANSSEN SUBMITS APPLICATION SEEKING APPROVAL OF SIRUKUMAB IN EUROPEAN UNION FOR RHEUMATOID ARTHRITIS

Beerse, Belgium, 12 September 2016 — Janssen-Cilag International NV (Janssen) announced today the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) seeking approval of sirukumab for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA). RA is a chronic, systemic inflammatory condition that affects approximately 6.2 million Europeans[1].

"*At Janssen, we are committed to continued innovation in the field of rheumatoid arthritis through new therapeutic options, like sirukumab, that address the medical needs of people living with moderately to severely active rheumatoid arthritis*", said Newman Yeilding, MD, Head of Immunology Development, Janssen Research & Development, LLC. "*We look forward to collaborating with the European health authorities with the goal of bringing sirukumab to patients living with rheumatoid arthritis who may benefit from this new biologic therapy*."

Data from the Phase 3 SIRROUND clinical development program, which includes five studies (SIRROUND-D, SIRROUND-T, SIRROUND-H, SIRROUND-M and SIRROUND-LTE), is incorporated into the submission. Results from the SIRROUND-D study were recently presented at the Annual European Congress of Rheumatology (EULAR 2016), and results from the SIRROUND-T and SIRROUND-H studies are planned to be presented later this year.

About the SIRROUND Clinical Program

The Phase 3 clinical program in patients with active RA includes five studies investigating subcutaneously administered sirukumab 50 mg every four weeks and sirukumab 100 mg every two weeks in combination with conventional disease-modifying antirheumatic drugs (DMARDs) or as monotherapy. The comprehensive development program involves more than 3,000 patients, comprising the following five studies:

- SIRROUND-D study: patients who had an inadequate response to DMARDs. This study is estimated to complete in 2017.
- SIRROUND-T study: patients who had an inadequate response or were intolerant to anti-TNFα agents. This study has completed.
- SIRROUND-H study: patients with an inadequate response or who were intolerant to methotrexate (MTX) or for whom MTX was inappropriate. This study has completed.
- SIRROUND-M study: Japanese patients who had an inadequate response to MTX or sulfasalazine. This study has completed.

- SIRROUND-LTE study: a long-term extension study for patients completing SIRROUND-D and SIRROUND-T. This study is estimated to complete in 2020. https://clinicaltrials.gov/ct2/show/NCT01856309.

About sirukumab

Sirukumab is a human monoclonal IgG1 kappa antibody that targets the cytokine IL-6, a naturally occurring protein that is believed to play a role in autoimmune conditions like RA. It is not approved as a treatment for RA or any other indication anywhere in the world.

About the Janssen-GlaxoSmithKline (GSK) Partnership

In December 2011, Janssen and GSK entered into a licensing and co-development agreement with respect to sirukumab. Under the terms, GSK has exclusive rights to commercialise sirukumab in North, Central and South America, while Janssen retains commercialisation rights in the rest of the world, including such territories as EMEA and Asia Pacific with global profit shared equally between the two companies. Prior to the agreement, Janssen had been developing sirukumab for RA.

As part of the collaboration, a Phase 3 program began in August 2012 to investigate sirukumab for the treatment of moderately to severely active RA. Janssen is responsible for the EMA regulatory file. The agreement gives both companies the option to investigate sirukumab for other indications beyond RA.

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic, systemic inflammatory condition that is characterised by pain, joint swelling, stiffness, joint destruction and disability. It is estimated that more than 23.5 million people worldwide are affected by the condition, for which there is no cure.[1]

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/EMEA. Follow us on Twitter: @JanssenEMEA.

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 including regulatory submissions seeking 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-Cilag International NV, Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies 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.

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[1] World Health Organization. "The Global Burden of Disease: 2004 Update," p. 32. Available at: http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. Accessed August 16, 2016.