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Siltuximab Receives CHMP Positive Opinion for use in the Treatment of Multicentric Castleman's Disease, a very Rare Blood Disorder

Beerse / Belgium, March 21, 2014 – Janssen-Cilag International NV ("Janssen") announced today that The Committee for Medical Products for Human Use (CHMP) of The European Medicines Agency (EMA) adopted a positive opinion recommending the granting of a marketing authorisation for siltuximab for the treatment of adult patients with multicentric Castleman's disease (MCD) who are HIV-negative and human herpes virus-8 (HHV-8)-negative.[1] If approved, siltuximab would be the first medicine to receive regulatory approval in the EU for treatment of MCD patients.

MCD is a very rare and complex blood disorder with high morbidity. It is a condition in which lymphocytes, a type of white blood cells, are over-produced, leading to enlarged lymph nodes. MCD can also affect lymphoid tissue of internal organs, causing the liver, spleen, or other organs to enlarge.[2] Infections, multisystem organ failure, and malignancies including malignant lymphoma are common causes of death in patients with MCD.[2,3,4]

The positive opinion of the CHMP is based on a review of data from a multinational, randomised, double-blind, placebo-controlled pivotal study (MCD2001) in 79 patients with MCD, along with data from two non-randomised supportive studies. The MCD2001 study assessed the safety and efficacy of siltuximab plus best supportive care (BSC) compared with placebo plus BSC in patients with MCD who are HIV-negative and HHV-8-negative. The primary endpoint of the study was durable tumour and symptomatic response, defined as tumour response assessed by independent review and complete resolution or stabilisation of prospectively collected MCD symptoms, for at least 18 weeks

without treatment failure. Secondary endpoints included additional predefined efficacy measures and safety.[5]

MCD2001 is the first randomised study in MCD.[5] Results showed that more than one-third of patients in the siltuximab arm had a durable tumour and symptomatic response to treatment plus BSC, compared to none of the patients who received placebo plus BSC (34 percent versus 0 percent; p=0.0012; based on central review). The median time to treatment failure was not reached for patients who received siltuximab plus BSC over 48 weeks of treatment; those who received placebo plus BSC experienced treatment failure at a median of 134 days (p=0.0084).[5]

“At Janssen, we are driven by our commitment to patients and to the research and development of innovative products,” said Jane Griffiths, Company Group Chairman of Janssen Europe, the Middle East and Africa (EMEA). “We are therefore very pleased with the CHMP positive opinion and are proud of our work on siltuximab, which has the potential to address an unmet need amongst MCD patients, for whom no approved treatment in the EU currently exists.”

Siltuximab was granted orphan drug status in MCD in both the EU and the United States (U.S.). A final decision for siltuximab is expected from the European Commission within the next three months.

On September 3, 2013, Janssen announced the submission of a Biologic License Application (BLA) to the U.S. Food and Drug Administration (U.S. FDA) for siltuximab for the treatment of patients with MCD who are HIV-negative and HHV-8-negative. The U.S. FDA accepted the submission and granted siltuximab priority review, which is currently ongoing.

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About siltuximab

Siltuximab is an anti-interleukin-6 (IL-6) chimeric monoclonal antibody that binds to human IL-6. IL-6 is a multifunctional cytokine produced by various cells such as T cells, B cells, monocytes, fibroblasts and endothelial cells. Dysregulated overproduction of IL-6 from activated B cells in affected lymph nodes has been implicated in the pathogenesis of, or mechanism causing, MCD.[6] Information about the ongoing study of siltuximab can be found at www.clinicaltrials.gov.

About multicentric Castleman's disease (MCD)

MCD is a proliferative disease that acts very much like lymphoma (cancer of lymph nodes). It is so rare that it is very difficult to track the number of cases.

MCD signs and symptoms are driven by dysregulated IL-6 production.[2,6] Many common symptoms include enlarged lymph nodes (appear as lumps under the skin), fever, weakness, fatigue, night sweats, weight loss, loss of appetite, nausea, vomiting and nerve damage that leads to numbness and weakness.[2] Some symptoms can be life threatening. Infections, multisystem organ failure, and malignancies including malignant lymphoma are common causes of death in patients with MCD.[2,3,4] Currently there are no approved treatments in the EU for MCD.

Unlike "unicentric" Castleman's disease, which is localised and affects only a single area or group of lymph nodes, patients with MCD have more than one group of lymph nodes in different anatomical areas that are affected. Unicentric disease can be treated by surgically removing the diseased lymph node, while multicentric disease is usually much more difficult to treat.[2,6]

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases. Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world. More information can be found at www.janssen-emea.com.

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on haematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualised use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

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(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding siltuximab. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; competition, including technological advances, new products and patents attained by competitors; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; and general industry conditions including trends toward health care cost containment. A further list and description 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 29, 2013, including in Exhibit 99 thereto, and our 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. Neither Janssen-Cilag International NV 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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