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Simultaneous Applications Submitted to FDA and EMA for Siltuximab for the Treatment of Multicentric Castleman Disease, a Rare Blood Disorder

RARITAN, NJ, September 3, 2013 - Janssen Research & Development, LLC ("Janssen") announced the simultaneous submissions of a Biologic License Application (BLA) to the United States Food and Drug Administration (U.S. FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for siltuximab for the treatment of patients with multicentric Castleman disease (MCD) who are HIV-negative and human herpes virus-8 (HHV-8)-negative.

MCD is a rare disorder in which lymphocytes, a certain type of white blood cells, are over-produced and lead to enlargement of lymph nodes.[1, 2] This can cause a variety of symptoms and weaken the immune system, making it hard to fight infection. Infections in people with MCD can be very serious and may even be fatal.[3] Currently, there are no approved treatments in the U.S. or European Union (EU) for this rare blood disorder.

"We're proud of our work on siltuximab. As a rare disease with a small patient population, MCD is an area of significant unmet need," said Peter F. Lebowitz, M.D., Ph.D., global oncology therapeutic area head, Janssen. "Siltuximab works by targeting interleukin-6 which appears to be the critical driver of this disease. By focusing on core biologic mechanisms, we now have the potential of helping patients with a condition that is challenging to treat."

Siltuximab has been granted orphan drug status in MCD in the U.S. and EU. The siltuximab regulatory submissions include data from a randomized, multi-national, double-blind, placebo-controlled study (MCD2001) and data from two non-randomized supportive studies. The MCD2001 study assessed the efficacy and safety of siltuximab plus best supportive care (BSC) compared with placebo plus BSC in patients with MCD.[4] In the study, 79 patients were randomly assigned in a 2:1 ratio to one of the two treatment groups, with 53 receiving siltuximab and BSC, and 26 receiving placebo and BSC.[5] Results of the primary study analysis have been submitted for presentation at a medical meeting later this year.

About Multicentric Castleman Disease

Unlike "unicentric" Castleman disease, which is localized and affects only a single area or group of lymph nodes,[6] patients with MCD have more than one group of lymph nodes in different anatomical areas that are affected.[3] Unicentric disease can be treated by surgically removing the diseased lymph node,[7] while multicentric disease is usually much more difficult to treat.[8] Currently, the focus of care is to reduce lymph node masses[9, 10] and to attempt to put the disease in remission through a combination of treatments, including corticosteroids, chemotherapy and immunotherapy. While such treatments may initially help, the disease often returns.[8]

MCD can also affect lymphoid tissue of internal organs, causing the liver, spleen, or other organs to enlarge.[11] Some symptoms can be life threatening.[9,10] The most common symptoms include fever, weakness, fatigue, night sweats, weight loss, loss of appetite, nausea, vomiting, and nerve damage that leads to numbness and weakness.[3] Infections, renal failure, and malignancies including malignant lymphoma and Kaposi's sarcoma are common causes of death in patients with MCD.[9,10] Castleman disease is formally diagnosed through a biopsy.[11] The number of people diagnosed with Castleman disease is unknown, but the disease is known to be rare.[12]

About Siltuximab

Siltuximab is an investigational, anti Interleukin-6 (IL-6) chimeric monoclonal antibody that targets and 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.[6] Dysregulated, or imbalanced, overproduction of IL-6 from activated B cells in affected lymph nodes has been implicated in the pathogenesis of MCD.[6] Information about ongoing studies with siltuximab can be found on clinicaltrials.gov.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

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 disease area strongholds that focus on hematologic malignancies and prostate cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment. While we continually strive to find new real-life solutions for cancer patients, the Janssen Pharmaceutical Companies can provide a broad offering throughout the cancer journey - from prevention, diagnosis, and treatment - to the return to wellness.

Janssen Research & Development is part of the Janssen Pharmaceutical Companies. Please visit http://www.janssenrnd.com for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; 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; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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