April 23, 2014

SYLVANT™ (siltuximab) Receives FDA Approval to Treat Multicentric Castleman's Disease (MCD)

First treatment approved for patients with rare blood disorder

HORSHAM, PA, April 23, 2014 - Janssen Biotech, Inc. ["Janssen"] today announced the U.S. Food and Drug Administration (FDA) has approved SYLVANT™ (siltuximab) for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. SYLVANT was not studied in patients with MCD who are HIV positive or HHV-8 positive because SYLVANT did not bind to virally produced interleukin-6 (IL-6) in a nonclinical study. SYLVANT is an IL-6 antagonist biologic therapy administered as an intravenous (IV) infusion once every three weeks.[1] SYLVANT is the first approved treatment in the U.S. for MCD.

MCD is a rare blood disorder with high morbidity in which lymphocytes, a type of white blood cell, 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. Infections, multisystem organ failure and malignancies including malignant lymphoma are common causes of death in patients with MCD.[2,3,4,5]

"There has been a serious need for treatment options for patients with MCD," said Frits van Rhee, M.D., Ph.D., University of Arkansas for Medical Sciences, and MCD2001 study lead investigator. "MCD is a complex disease and up until this point, physicians have tried to reduce lymph node masses and put the disease in remission through a combination of treatments, but MCD often returns. Today's approval of SYLVANT gives physicians a long-awaited treatment option for a group of patients who has been suffering with this chronic, serious and debilitating disease."

"Today's approval of a treatment for patients with multicentric Castleman's disease marks a significant milestone for patients living with this rare disease and underscores the importance of ongoing research and development in areas where there are so few patients with such a high unmet medical need," said Peter L. Saltonstall, president and CEO, National Organization of Rare Disorders (NORD), a federation of health organizations dedicated to helping people with rare diseases.

While the cause of MCD currently is unknown, overproduction of IL-6 is considered a key mechanism in MCD.[2,7] SYLVANT works by binding to human IL-6, a multifunctional cytokine produced by various cells such as T cells, B cells, monocytes, fibroblasts and endothelial cells.[1,7]

"SYLVANT exemplifies Janssen's approach to research and development, as well as our commitment to patients," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "Our expertise in hematologic malignancies was key to recognizing the potential for SYLVANT in this rare disease. We're extremely proud to be the first company with an approved medicine to treat MCD in the U.S."

About the MCD2001 Pivotal Study
The efficacy and safety of SYLVANT were evaluated in a multi-national, randomized, double-blind, placebo-controlled pivotal study in 79 patients with MCD (MCD2001). MCD2001 is the first randomized study in MCD.[8] Fifty-three patients were randomized to the SYLVANT arm at a dose of 11 mg/kg and 26 patients were randomized to the placebo arm. Patients had symptomatic MCD and were HIV negative and HHV-8 negative.[1]

Treatment of MCD tumors and related symptoms is an important treatment goal for these patients. In this pivotal study, which led to the FDA approval, more than one-third of patients in the SYLVANT arm had a durable tumor and symptomatic response to treatment plus best supportive care (BSC), compared to none of the patients who received placebo plus BSC (34 percent versus 0 percent; 95 percent CI: 11.1, 54.8; p=0.0012). A durable response was defined as tumor and symptomatic response (reduction in tumor size and disease symptoms) that persisted for a minimum of 18 weeks without treatment failure. The median time to treatment failure was not reached for patients who received SYLVANT plus BSC; those who received placebo plus BSC experienced treatment failure at a median of 134 days ($p<0.05$). Efficacy results from MCD2001 also showed tumor response for those in the SYLVANT arm was 38 percent versus four percent for those in the placebo arm ($p<0.05$). Among anemic patients, an increase in hemoglobin of 1.5 g/dL was seen in 61 percent of patients in the SYLVANT arm versus 0 percent in patients who received placebo and BSC ($p<0.05$).

The warnings and precautions for SYLVANT include concurrent active severe infections, administration of live vaccines, infusion

related reactions and hypersensitivity and gastrointestinal perforation.[1] For more information about warnings and precautions, please see below in this press release.

The most frequent adverse reactions (greater than 10 percent compared to placebo) during treatment with SYLVANT in the MCD clinical trial were rash (28 percent), pruritus (itching) (28 percent), upper respiratory tract infection (26 percent), increased weight (19 percent) and hyperuricemia (high uric acid level) (11 percent).[1]

*Estimate from a U.S. claims database

Access to SYLVANT

Janssen Biotech is committed to helping patients obtain access to our medicines by offering comprehensive access services and support for patients. The SylvantOne™ Support program offers a variety of services for providers and patients that can help assess insurance coverage and identify cost support options, such as the SylvantOne™ Patient Rebate Program for eligible commercial patients, as well as a potential option for those who are uninsured. Patients and providers can contact SylvantOne™ Support by calling 1-855-299-8844.

About SYLVANT™ (siltuximab)

SYLVANT is an anti-interleukin-6 (IL-6) chimeric monoclonal antibody that binds to human IL-6.[1] 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.[7] Information about ongoing studies with siltuximab can be found at www.clinicaltrials.gov.

On September 3, 2013, Janssen announced 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 MCD who are HIV negative and HHV-8 negative. The FDA granted the siltuximab BLA priority review in the U.S. and the EMA has granted Accelerated Assessment of the MAA. Siltuximab has been granted orphan drug status in MCD in the U.S. and European Union.

About multicentric Castleman's disease (MCD)

MCD is a rare blood disorder with high morbidity in which lymphocytes, a type of white blood cell, are over-produced and lead to enlargement of lymph nodes. MCD can also affect lymphoid tissue of internal organs, causing the liver, spleen or other organs to enlarge.[2] Signs and symptoms are driven by dysregulated IL-6 production.[2,7] Common symptoms include enlarged lymph nodes (appearing 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.[2,3,4,5]

Unlike "unicentric" Castleman's disease, which is localized 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.[2,7]

Castleman's disease is formally diagnosed through a lymph node biopsy. The number of people diagnosed with Castleman's disease is unknown, but the disease is known to be rare.[2]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS - Severe hypersensitivity reaction to siltuximab or any of the excipients in SYLVANT.

Concurrent Active Severe Infections - Do not administer to patients with severe infections until the infection resolves. Monitor patients closely for infections. Institute prompt anti-infective therapy and do not administer further SYLVANT until the infection resolves.

Vaccinations - Do not administer live vaccines to patients receiving SYLVANT because interleukin-6 (IL-6) inhibition may interfere with the normal immune response to new antigens.

Infusion Related Reactions and Hypersensitivity - Stop the infusion if the patient develops signs of anaphylaxis. Discontinue further therapy.

Stop the infusion if the patient develops mild to moderate infusion reactions. If the reaction resolves, the infusion may be restarted at a lower infusion rate. Consider medicating with antihistamines, acetaminophen, and corticosteroids. Discontinue

SYLVANT if the patient does not tolerate the infusion following these interventions. [see Adverse Reactions (6)].

Administer SYLVANT in a setting that provides resuscitation equipment, medication, and personnel trained to provide resuscitation.

Gastrointestinal (GI) Perforation - Use with caution in patients who may be at increased risk for GI perforation. Promptly evaluate patients presenting with symptoms that may be associated or suggestive of GI perforation.

Adverse Reactions - The most common adverse reactions (>10% compared to placebo) in the clinical trial were pruritus, increased weight, rash, hyperuricemia, and upper respiratory tract infection.

Drug Interactions - Cytochrome P450 (CYP450) Substrates - Upon initiation or discontinuation of SYLVANT, in patients being treated with CYP450 substrates with narrow therapeutic index, perform therapeutic monitoring of effect (e.g., warfarin) or drug concentration (e.g. Cyclosporine or theophylline) as needed and adjust dose. Exercise caution when SYLVANT is co administered with CYP3A4 substrate drugs where a decrease in effectiveness would be undesirable (e.g., oral contraceptives, lovastatin, atorvastatin).

More information about SYLVANT will be available soon at www.SYLVANT.com. Please see U.S. full Prescribing Information.

About Janssen Biotech, Inc.
Janssen Biotech, Inc. redefines the standard of care in immunology, oncology, urology and nephrology. Built upon a rich legacy of innovative firsts, Janssen Biotech has delivered on the promise of new treatments and ways to improve the health of individuals with serious disease. Beyond its innovative medicines, Janssen Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care. For more information on Janssen Biotech, Inc. or its products, visit www.janssenbiotech.com.

Janssen Biotech is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, cardiovascular and metabolic diseases. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to people throughout the world. Follow us on Twitter at www.twitter.com/JanssenUS.

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 hematologic 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, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding SYLVANTTM (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 Biotech, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals and successfully marketing and selling products; competition, including technological advances, new products and patents attained by competitors; 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; 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. 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] SYLVANT™ (siltuximab) Prescribing Information. April 2014.

[2] American Cancer Society. Castleman disease. Last updated June 2012. Available from: http://www.cancer.org/acs/groups/cid/documents/webcontent/003093-pdf.pdf. Accessed April 2014.

[3] Peterson, B. Multicentric Castleman's disease. Seminars in Oncology. 1993;20(6):636-47. Available from:

http://www.ncbi.nlm.nih.gov/pubmed/8296200. Accessed April 2014.

[4] Greiner, T. Atypical Lymphoproliferative Diseases. Hematology Am Soc Hematol Educ Program. 2000:133-146. Available from: http://www.ncbi.nlm.nih.gov/pubmed/11701539. Accessed April 2014.

[5] Van Rhee F et al. Castleman Disease in the 21st Century: An Update on Diagnosis, Assessment, and Therapy. Clinical Advances in Hematology & Oncology. 2010;8(7):486-98.

[6] Mehra M et al. Use of a Claims Database to Characterize and Estimate the Incidence of Castleman's Disease. Poster presented at: 54th American Society of Hematology (ASH) Annual Meeting and Exposition; Dec. 8-11, 2012; Atlanta, GA.

[7] El-Osta HE, Kurzrock R. Castleman's disease: from basic mechanisms to molecular therapeutics. Oncologist. 2011;16(4):497-511.

[8] Wong RS et al. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Of The Efficacy and Safety Of Siltuximab, An Anti-Interleukin-6 Monoclonal Antibody, In Patients With Multicentric Castleman's Disease. Oral presentation presented at: 55th American Society of Hematology (ASH) Annual Meeting; Dec. 7-11, 2013; New Orleans, LA.

U.S. Media Inquiries:
Megan Farina
Phone: 1-215-325-6861
Mobile: 1-610-724-1079

Kellie McLaughlin
Phone: 1-908-927-7477
Mobile: 1-609-468-8356

Investor Relations:
Stan Panasewicz
Phone: 1-732-524-2524

Louise Mehrotra
Phone: 1-732-524-6491

U.S. Medical Inquiries:
1-800-526-7736