Press Releases

June 12, 2020

Kite Receives European Medicines Agency Approval for CAR T Cell Therapy Manufacturing Facility in Europe

-- Amsterdam Facility will Bring Kite's Potentially Life-Saving Individualized Treatment Closer to People with Advanced Blood Cancers in the European Region --

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite, a Gilead Company (Nasdaq: GILD), today announced it has received approval to implement a variation to the Yescarta® (axicabtagene ciloleucel) Marketing Authorization from the European Medicine Agency (EMA) for end-to-end manufacturing. With this approval, Kite's European manufacturing facility, designed and dedicated to the manufacture of individualized cell therapies, is now fully operational.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200612005018/en/

Kite's European cell therapy manufacturing facility, located outside of Amsterdam. (Photo: Business Wire)

"Kite is focused foremost on the needs of patients living with cancer and we are proud to now manufacture cell therapy directly in Europe," said Christi Shaw, Chief Executive Officer of Kite. "This facility will benefit both patients and healthcare professionals, allowing Yescarta to reach European treatment centers more quickly and reducing the time it takes to reach patients by almost a week."

Kite has nearly 90 qualified treatment centers in 16 countries across Europe and Israel. The new European facility sits next to one of Europe's largest airports, Amsterdam

Airport Schiphol. This central location, with its transport links to the region, will reduce the delivery time to and from treatment centers. The facility has the capacity to produce therapy for up to 4,000 patients per year.

“With the enhanced technology and processes at our new facility we are pleased to be leading the next chapter in the manufacture and delivery of CAR T therapy,” said Charles Calderaro, Kite’s Global Head of Technical Operations. “Our new European manufacturing facility is dedicated to cutting-edge cell engineering, enabling patients to receive their potentially life-saving treatment more quickly.”

“The prognosis for patients with refractory large B-cell lymphoma is poor, with a median survival of approximately six months with the prior standard of care,” said Marie José Kersten, MD, PhD, Amsterdam University Medical Centers, Amsterdam, the Netherlands. “Timely access to cell therapy is critical, and the ability to manufacture CAR T cell therapies in Europe is welcomed by the clinical community.”

About Kite’s Cell Therapy Manufacturing Network

As the leader in engineered cell therapy, Kite has set a standard with an integrated state-of-the-art global manufacturing network that includes commercial manufacturing facilities in El Segundo, California and Amsterdam, and clinical manufacturing in Santa Monica, California and Gaithersburg, Maryland. Kite is also building a third commercial cell therapy manufacturing facility in Frederick County, Maryland, which will significantly expand the company’s ability to manufacture CAR T cell therapies. In addition to producing novel CAR T cell therapies, the clinical manufacturing network is also producing investigational T cell receptor therapies for evaluation in solid tumors. A new facility in Oceanside, California is also under construction and will be dedicated to the development and manufacturing of viral vectors, a critical starting material in the production of cell therapies.

About Yescarta® (axicabtagene ciloleucel)

Yescarta was the first CAR T cell therapy to be approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, and high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma. The Yescarta U.S. Prescribing Information has a BOXED WARNING for the risks of cytokine release syndrome (CRS) and neurologic toxicities, and Yescarta is approved with a risk evaluation and mitigation strategy (REMS) due to these risks; see below for Important Safety Information.

Yescarta is also approved in the European Union as a treatment for adult patients with

Yescarta is also approved in the European Union as a treatment for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy.

U.S. Important Safety Information for Yescarta

BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving Yescarta. Do not administer Yescarta to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving Yescarta, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with Yescarta. Provide supportive care and/or corticosteroids as needed.**
- **Yescarta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta REMS.**

CYTOKINE RELEASE SYNDROME (CRS) occurred in 94% of patients, with 13% ≥ Grade 3. Among patients who died after receiving Yescarta, 4 had ongoing CRS at death. The median time to onset was 2 days (range: 1-12 days) and median duration was 7 days (range: 2-58 days). Key manifestations include fever (78%), hypotension (41%), tachycardia (28%), hypoxia (22%), and chills (20%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome. Ensure that 2 doses of tocilizumab are available prior to Yescarta infusion. Following infusion, monitor patients for signs and symptoms of CRS at least daily for 7 days at the certified healthcare facility, and for 4 weeks thereafter. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as indicated.

NEUROLOGIC TOXICITIES occurred in 87% of patients, 98% of which occurred within the first 8 weeks with a median time to onset of 4 days (range: 1-43 days) and a median duration of 17 days. Grade ≥3 occurred in 31% of patients. The most common neurologic toxicities included encephalopathy (57%), headache (44%), tremor (31%), dizziness (21%), aphasia (18%), delirium (17%), insomnia (9%), and anxiety (9%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including leukoencephalopathy and seizures, as well as fatal and serious cases of cerebral edema have occurred. Following Yescarta infusion, monitor patients for signs and symptoms of neurologic toxicities at least daily for 7 days at the certified healthcare facility, and for 4 weeks thereafter, and treat promptly.

treat promptly.

REMS: Because of the risk of CRS and neurologic toxicities, Yescarta is available only through a restricted program called the Yescarta REMS which requires that: Healthcare facilities that dispense and administer Yescarta must be enrolled and comply with the REMS requirements and must have on-site, immediate access to a minimum of 2 doses of tocilizumab for each patient for infusion within 2 hours after Yescarta infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer Yescarta are trained about the management of CRS and neurologic toxicities. Further information is available at www.YESCARTAREMS.com or 1-844-454-KITE (5483).

HYPERSENSITIVITY REACTIONS: Allergic reactions, including serious hypersensitivity reactions or anaphylaxis, may occur with the infusion of Yescarta.

SERIOUS INFECTIONS: Severe or life-threatening infections occurred. Infections (all grades) occurred in 38% of patients. Grade ≥3 infections occurred in 23% of patients; those due to an unspecified pathogen occurred in 16% of patients, bacterial infections in 9%, and viral infections in 4%. Yescarta should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after infusion and treat appropriately. Administer prophylactic anti-microbials according to local guidelines. Febrile neutropenia was observed in 36% of patients and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids, and other supportive care as medically indicated. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

PROLONGED CYTOPENIAS: Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and Yescarta infusion. Grade ≥3 cytopenias not resolved by Day 30 following Yescarta infusion occurred in 28% of patients and included thrombocytopenia (18%), neutropenia (15%), and anemia (3%). Monitor blood counts after infusion.

HYPOGAMMAGLOBULINEMIA and B-cell aplasia can occur. Hypogammaglobulinemia occurred in 15% of patients. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following Yescarta treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during Yescarta treatment, and until immune recovery following treatment.

SECONDARY MALIGNANCIES [illegible]

SECONDARY MALIGNANCIES may develop. Monitor life-long for secondary malignancies. In the event that one occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following Yescarta infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

ADVERSE REACTIONS: The most common (incidence ≥20%) include CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.

About Kite

Kite, a Gilead Company, is a biopharmaceutical company based in Santa Monica, California. Kite is engaged in the development of innovative cancer immunotherapies. The company is focused on chimeric antigen receptor and T cell receptor engineered cell therapies. For more information on Kite, please visit www.kitepharma.com.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward-Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Kite's ability to timely manufacture and deliver CAR T cell therapy to patients in Europe. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead and Kite, and Gilead and Kite assume no

obligation to update any such forward-looking statements.

*U.S. Prescribing Information for Yescarta, including **BOXED WARNING**, is available at www.kitepharma.com and www.gilead.com.*

Full European Summary of Product Characteristics for Yescarta® is available from the EMA website at www.ema.europa.eu.

Yescarta is a registered trademark of Gilead Sciences, Inc., or its related companies.

For more information on Kite, please visit the company's website at www.kitepharma.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000. Follow Kite on social media on Twitter (@KitePharma) and LinkedIn.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200612005018/en/

Douglas Maffei, PhD, Investors
(650) 522-2739

Nathan Kaiser, Media
(650) 522-1853

Source: Kite, a Gilead Company