



Yescarta® (Axicabtagene Ciloleucel) Receives European Marketing Authorization for the Treatment of Relapsed or Refractory DLBCL and PMBCL, After Two or More Lines of Systemic Therapy

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-- New Option for Adult Patients in Europe as Axicabtagene Ciloleucel Becomes the First CAR T to Receive European Approval for Two Types of Aggressive Non-Hodgkin Lymphoma --

SANTA MONICA, Calif.--(BUSINESS WIRE)--Aug. 27, 2018-- Kite, a Gilead Company (Nasdaq: GILD), today announced that the European Commission (EC) has granted Marketing Authorization for Yescarta® (axicabtagene ciloleucel) 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. The Marketing Authorization approves axicabtagene ciloleucel for use in the 28 countries of the European Union, Norway, Iceland and Liechtenstein.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20180827005248/en/>

Axicabtagene ciloleucel is a chimeric antigen receptor T cell (CAR T) therapy, which harnesses a patient's own immune system to fight certain types of blood cancer. The cell therapy has been proven to induce complete response (no detectable cancer) in a proportion of patients with relapsed or refractory DLBCL and PMBCL, which are aggressive forms of non-Hodgkin lymphoma (NHL).

"Axicabtagene ciloleucel is a new and exciting way of treating cancer that offers a new option to patients with DLBCL and PMBCL in Europe," said Professor Gilles Salles, Head of Hematology, South Lyon Hospital Complex. "Many patients with these aggressive forms of non-Hodgkin lymphoma who have not responded to or failed commonly available treatment options have a very poor prognosis and there is an urgent need for new therapies."

The Marketing Authorization Application (MAA) is supported by data from the ZUMA-1 trial of axicabtagene ciloleucel in adult patients with refractory aggressive NHL. In the single-arm trial, 72 percent of patients (n=73/101) who received a single infusion of axicabtagene ciloleucel responded to therapy, with 51 percent (n=52/101) achieving a complete response (as assessed by an independent review committee, median follow-up of 15.1 months). At one year following infusion, 60 percent of patients were alive (95% CI: 50.2, 69.2) and the median overall survival (OS) had not been reached (95% CI: not estimable [NE]).

Axicabtagene ciloleucel may cause side effects that are severe or life threatening, such as cytokine release syndrome (CRS) or neurological toxicities. In ZUMA-1, 12 percent of patients experienced Grade 3 or higher CRS and 31 percent experienced Grade 3 or higher neurologic toxicities. Overall 98 percent of patients recovered from CRS and/or neurologic adverse reactions. Treatment algorithms have been developed to manage some of the symptoms associated with both CRS and neurologic adverse reactions experienced by patients on axicabtagene ciloleucel.

The most common Grade 3 or higher adverse reactions include encephalopathy, unspecified pathogen infection, CRS, bacterial infection, aphasia, viral infection, delirium, hypotension and hypertension.

For full details on the Special Warnings and Precautions for Use and Adverse Reactions (including appropriate management) please refer to the EU Summary of Product Characteristics (SmPC).

"We are proud to be leading this frontier of cancer innovation that is bringing novel, personalized therapy to people living with these blood cancers," said Alessandro Riva, MD, Gilead's Executive Vice President, Oncology Therapeutics & Head, Cell Therapy. "Our vision is for cell therapy to serve as the foundation for treating all cancer types. Today's milestone is another step on this exciting and important journey."

Axicabtagene ciloleucel was approved by the U.S. Food and Drug Administration on October 18, 2017.

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 Statements

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 the risk that physicians may not see the benefits of prescribing axicabtagene ciloleucel for the treatment of DLBCL and PMBCL and the possibility of unfavorable results from additional clinical trials involving axicabtagene ciloleucel. 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 June 30, 2018, 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.

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. Learn more about Gilead at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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