Kowa Pharmaceuticals America and Lilly Announce U.S. Availability of LIVALO

Statin Available to Treat Patients with Primary Hyperlipidemia or Mixed Dyslipidemia

MONTGOMERY, Ala. and INDIANAPOLIS, June 21, 2010 /PRNewswire via COMTEX News Network/ -- Kowa Pharmaceuticals America, Inc., and Eli Lilly and Company (NYSE: LLY) today announced that LIVALO(R) (pitavastatin) tablets is now available in retail pharmacies throughout the United States. LIVALO, a statin medication approved by the U.S. Food and Drug Administration (FDA) in August 2009 is indicated for adults as an adjunctive therapy to diet for the treatment of primary hyperlipidemia or mixed dyslipidemia. LIVALO is available in doses of 1 mg, 2 mg and 4 mg.

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LIVALO, approved on the basis of 10 clinical trials, including five 12-week clinical trials comparing efficacy and safety to three currently FDA-approved statins (atorvastatin, simvastatin, and pravastatin), offered LDL cholesterol (LDL-C) lowering of up to 39 percent at a 2 mg dose and up to 45 percent at a 4 mg dose.

While few drugs, including LIVALO, are free from drug-drug interactions, LIVALO may be an attractive option for physicians treating patients taking multiple medications because its potential for cytochrome P450-mediated drug-drug interactions is low. LIVALO is only minimally metabolized by the cytochrome P450 system in the liver, which is important because this system is involved in approximately 75 percent of all drug metabolism.(1)

"Since many patients treated for elevated cholesterol may be on multiple medications, it is important that physicians and pharmacists caring for these patients understand how treatment with a cholesterol medication, such as a statin, may potentially interact with the other drugs the patient may be taking," said Michael Davidson, M.D. Director of Preventive Cardiology, University of Chicago Pritzker School of Medicine.

"LIVALO has been the leading product in our cardiovascular portfolio in Asia since 2003," said Ben Stakely, president and CEO of Kowa Pharmaceuticals. "We are excited to bring our flagship product to the U.S. to help patients reach their LDL-C goals."

"Lilly is committed to providing innovative solutions to patients in need and is excited to collaborate with Kowa Pharmaceuticals America, Inc. to bring this new statin to the market," said Javan Collins, vice president of Cardiovascular Business Unit, Lilly. "LIVALO offers physicians another option for patients trying to lower their LDL-C."

Kowa Pharmaceuticals and Lilly last year announced a co-promotion agreement to commercialize LIVALO in the U.S. in which both companies will provide sales force resources and share development and commercialization costs.

About LIVALO

LIVALO is a synthetic statin developed in Japan. The efficacy of LIVALO has been evaluated against atorvastatin, simvastatin, and pravastatin in patients with primary hyperlipidemia or mixed dyslipidemia. In these studies, LIVALO was evaluated in patients with Type II diabetes, patients 65 years and over, and patients with two or more risk factors for coronary artery disease. LIVALO is only minimally metabolized by the liver cytochrome P450 enzyme system, which may help reduce its potential for drug-drug interactions mediated by this system.

Since its launch in Japan (2003), South Korea (2005), Thailand (2008) and China (2009), LIVALO has been successfully used in these countries to treat elevated cholesterol.

About Hyperlipidemia and Mixed Dyslipidemia

An elevated level of cholesterol in the blood is called hypercholesterolemia, commonly referred to as high cholesterol. It can be also defined as hyperlipidemia (high levels of fatty substances in the blood). High level of triglycerides also falls under this category. Mixed dyslipidemia is usually marked by an elevation of total cholesterol, LDL-C, and triglyceride (TG) levels and a decrease in HDL-C in the blood.

Despite the availability of treatments in the U.S., there is still a need for more options to help treat elevated cholesterol. According to the American Heart Association, approximately one out of every three American adults has an LDL-C level of 130 mg/dL or higher, which is a major risk factor for coronary heart disease (CHD) and stroke. In addition, less than half of patients who qualify for any kind of lipid-modifying treatment are receiving it, and only about one-third of patients who are on treatment are achieving their LDL-C goals.

LIVALO Important Safety Information

LIVALO is not right for everyone, including, patients who previously have had an allergic reaction to LIVALO or any of its components, anyone with active liver problems, those with severe kidney disease not yet on hemodialysis, or women who are nursing, pregnant or who may become pregnant.

Patients should not take LIVALO if they are taking cyclosporine.

Patients taking LIVALO should tell their doctor immediately if they experience any unexplained muscle pain, tenderness or weakness, particularly if accompanied by fever or a general feeling of discomfort. This could be a sign of a rare but serious side effect.

It is recommended that physicians conduct blood tests to monitor patient's liver function before starting LIVALO, at 12 weeks following the start of LIVALO or after any increase in dose and then periodically (e.g., every six months) thereafter.

The most common side effects of LIVALO in clinical studies were muscle pain, back pain, constipation, diarrhea and pain in the legs or arms. This is not a complete list of side effects.

LIVALO has not been studied to understand its effect in reducing heart-related disease or death.

Patients should tell their doctor about all the medications they take, including all prescription and nonprescription medicines, vitamins or herbal supplements.

For more information about LIVALO, please see the Full Prescribing Information at (http://www.livalorx.com/documents/LIVALOpitavastatinprescribinginformationV1_220100131.pdf). You may also learn more about LIVALO at www.LIVALORx.com.

About Kowa Company, Ltd. and Kowa Pharmaceuticals America, Inc.

Kowa Company, Ltd. (KCL) is a privately held multinational company headquartered in Nagoya, Japan. Established in 1894, KCL is actively engaged in various manufacturing and commercial activities in the fields of pharmaceutical, life science, information technology, textiles, machinery and various consumer products. KCL's pharmaceutical division is focused on cardiovascular therapeutics, with sales of the company's flagship product LIVALO, totaling $399 million (12.8% market share) in Japan in 2009 and is expected to exceed $600 million in the near future.

Kowa Pharmaceuticals America, Inc. (KPA) is a specialty pharmaceutical company focused primarily in the area of cardiometabolic therapeutics. The company, started in 2001 as ProEthic Pharmaceuticals, Inc., was acquired by KCL in September of 2008. A privately held company, KPA focuses its efforts on the acquisition, development, licensing and marketing of pharmaceutical products.

For more information about KPA, please visit www.kowapharma.com.

About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This news release contains forward-looking statements. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, Lilly and Kowa' abilities to successfully commercialize and market

LIVALO, competition from other pharmaceutical companies (including generic versions of other statin products), potential regulatory developments affecting the product, and other factors described in Lilly's most recent filings with the Securities and Exchange Commission. For additional information about the factors that affect the company's business, please see Lilly's latest Form 10-K, filed February 2009, and Form 10-Q filed October 2009. Lilly undertakes no duty to update forward-looking statements.

LIVALO is a registered trademark of the Kowa group of companies.

(1) F. Peter Guengerich; Cytochrome P450 and Chemical Toxicology. Chem. Res. Toxicol. 2008, 21, 70-83.

SOURCE Kowa Pharmaceuticals America, Inc.; Eli Lilly and Company