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FDA APPROVES TRIBENZOR™, A NEW THREE-IN-ONE COMBINATION PRODUCT FOR THE TREATMENT OF HIGH BLOOD PRESSURE

One in Three US Adults Have Hypertension and Many Are Uncontrolled on Two or More Antihypertensive Medications[1]

Parsippany, NJ – July 26, 2010 – Daiichi Sankyo, Inc. announced today that the U.S. Food and Drug Administration (FDA) approved TRIBENZOR™ (olmesartan medoxomil, amlodipine, hydrochlorothiazide), a new three-in-one combination product taken once-daily for the treatment of hypertension in patients who are not adequately controlled on any two of the following antihypertensive drug classes: angiotensin receptor blockers, calcium channel blockers and diuretics. TRIBENZOR is not indicated for initial therapy.[2]

Approximately 56 percent of patients taking current blood pressure-lowering therapies do not reach current recommended blood pressure goal of <140/90 mm Hg or <130/80 mm Hg for patients with diabetes, chronic renal disease, or chronic cardiovascular disease.[1,3] More than two-thirds of patients with high blood pressure will require two or more antihypertensive medications in order to achieve goal blood pressure control.[1]

A fixed-dose combination treatment, TRIBENZOR, simplifies dosing regimens, reduces pill burden and has the potential to lower co-pays for patients that require three medications to keep blood pressure within recommended levels.[1] Research also shows that the use of fixed-dose antihypertensive combination treatments may improve patient compliance as compared to taking each medication separately.[4]

"Generally speaking, it can be a struggle for some patients who need to take multi-pill regimens to take their medications as prescribed," said Joseph L. Izzo, MD, Chief of Medicine, Erie County Medical Center, Buffalo, NY. "TRIBENZOR is a three-in-one pill that offers a simple, convenient and consistently effective therapy for patients, and may be just what some patients need to help bring their blood pressure to goal."

TRIBENZOR combines three widely prescribed antihypertensive medications, each working in a different way, to lower blood pressure.[2] It combines the complementary actions of olmesartan medoxomil (which blocks angiotensin II receptors), amlodipine (which inhibits the entrance of calcium into the blood vessel walls), and hydrochlorothiazide (a diuretic which reduces water volume in the blood).[2] Together these three medications allow blood vessels to relax so that blood can flow more easily.[2]

After eight weeks of treatment, TRIBENZOR produced highly statistically significantly greater reductions in both systolic and diastolic blood pressures compared to each of the three dual combination therapies. According to the TRIBENZOR pivotal registration trial that included a total of 2,492 patients with hypertension (mean baseline blood pressure 168.5/100.9 mm Hg), the switch to TRIBENZOR 40/10/25 mg from each of the following three dual combination therapies: (i) amlodipine/ hydrochlorothiazide 10/25 mg, (ii) olmesartan/hydrochlorothiazide 40/25 mg, and (iii) olmesartan/ amlodipine 40/10 mg, yielded a further mean reduction after eight weeks of treatment in systolic blood pressure/diastolic blood pressure of 8.1/5.4 mm Hg, 7.6/5.4 mm Hg, and 8.4/4.5 mm Hg, respectively ($P<0.0001$ vs. each dual combination therapy).[2]

"Our comprehensive cardiovascular product portfolio provides a variety of treatment options to patients in a number of disease categories including hypertension, heart disease, diabetes and cholesterol," said Joseph P. Pieroni, President and CEO of Daiichi Sankyo, Inc. "Although hypertension is a mature category, the differences among patients will continue to support the need for differentiated products to achieve optimal results. The approval of TRIBENZOR shows Daiichi Sankyo is committed to optimizing individual patient care."

The most common adverse reactions (incidence ≥2 percent) seen in clinical trials for TRIBENZOR were dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling.[2]

For more information about TRIBENZOR, including full prescribing information, please visit www.tribenzor.com.

About Hypertension

Hypertension, also known as high blood pressure, is called the "silent killer" because it has no specific symptoms and increases the risk of cardiovascular and renal related diseases such as stroke, heart attack, heart and kidney failure.[5] Hypertension is one of the most prevalent conditions in the United States affecting almost one in three adults.[2] The cause of 90 to 95 percent of the cases of high blood pressure isn't known; however, high blood pressure is easily detected and usually controllable.[2]

IMPORTANT SAFETY INFORMATION ABOUT TRIBENZOR

WARNING: AVOID USE IN PREGNANCY
When pregnancy is detected, discontinue TRIBENZOR as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. See WARNINGS AND PRECAUTIONS. Fetal/Neonatal Morbidity and Mortality.

Contraindications

TRIBENZOR is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

Hypotension in Volume- or Salt-Depleted Patients
In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients, symptomatic hypotension due particularly to the olmesartan component may occur after initiation of treatment with TRIBENZOR. Treatment should start under close medical supervision.

Increased Angina and Myocardial Infarction
Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase.

Impaired Renal Function
Avoid use in patients with severely impaired renal function (creatinine clearance ≤30 mL/min). If progressive renal impairment becomes evident, consider withholding or discontinuing TRIBENZOR.

In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported. There has been no long-term use of olmesartan medoxomil in patients with unilateral or bilateral renal artery stenosis, but similar effects would be expected with TRIBENZOR because of the olmesartan medoxomil component.

Thiazides may precipitate azotemia in patients with renal disease. Cumulative effects of the drug may develop in patients with impaired renal function.

Hepatic Impairment
Avoid use in patients with severely impaired hepatic function.

Amlodipine is extensively metabolized by the liver and the plasma elimination half-life (t1/2) is 56 hours in patients with severely impaired hepatic function.

Minor alterations of fluid and electrolyte balance due to hydrochlorothiazide may precipitate hepatic coma.

Electrolyte and Metabolic Imbalances
Due to the hydrochlorothiazide component, observe patients for clinical signs of fluid or electrolyte imbalance.

Hypersensitivity Reaction
Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such history.

Systemic Lupus Erythematosus
Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus.

Vasodilation
Although vasodilation attributable to amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration. Patients with severe aortic stenosis may be at particular risk.

Lithium Interaction
Lithium generally should not be given with thiazides.

Adverse Reactions
The most frequently reported adverse reaction was dizziness (5.8 to 8.9%). The other most frequent adverse reactions occurring in greater than or equal to 2% of patients treated with TRIBENZOR are peripheral edema (7.7%), headache (6.4%), fatigue (4.2%), nasopharyngitis (3.5%), muscle spasms (3.1%), nausea (3.0%), upper respiratory tract infection (2.8%), diarrhea (2.6%), urinary tract infection (2.4%), and joint swelling (2.1%).

About Daiichi Sankyo

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

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