Daiichi Sankyo's U.S. Products Liability Litigation Settlement Program Moves Forward; More than 97 Percent of Eligible Litigants and Claimants Opt In

Tokyo, Japan and Basking Ridge, NJ – June 6, 2018 – Daiichi Sankyo Company, Limited and Daiichi Sankyo, Inc. announced today that more than 97 percent of eligible claimants have opted into the product liability litigation settlement program announced on August 1, 2017 for cases brought against various Daiichi Sankyo and Forest entities. These cases are related to olmesartan products (Benicar, Benicar HCT, Azor and Tribenzor) and allegations that such products caused sprue-like enteropathy and other severe gastro-intestinal symptoms.

The settlement program required, among other thresholds, that at least 97 percent of all eligible litigants and claimants decided to opt into the settlement and completed the required submissions. Now that this and other thresholds have been met, following a review by the Claims Administrator as set out in the settlement agreement, claimants who meet the specified criteria will receive payouts from the settlement fund, which is capped at $358 million. The amount of any payment to any claimant will be determined by a settlement matrix that takes injury level and other factors into account.

The impact to the financial position of the company is not considered material because the settlement fund is expected to be comprised primarily of proceeds from several of Daiichi Sankyo Group companies' insurance policies and supplemented with company funds to satisfy retentions.

Daiichi Sankyo takes all matters of patient safety seriously and remains firmly committed to our medications that contain olmesartan medoxomil. The company believes that this settlement program is in the best interest of all parties and allows the company to focus on bringing to market innovative medicines that help people live healthy and meaningful lives. Daiichi Sankyo continues to believe that the claims made in this litigation are without merit, and does not admit liability.

Olmesartan medoxomil is an angiotensin II receptor blocker (ARB) approved for the treatment of high blood pressure, alone or with other antihypertensive agents, and is one of eight marketed ARB drugs. The olmesartan medoxomil family of products used for the treatment of hypertension has a well-established safety profile with more than 53 million patient-years of use worldwide since 2002.

Important Safety Information for BENICAR®, BENICAR HCT®, AZOR®, and TRIBENZOR®

WARNING: FETAL TOXICITY

When pregnancy is detected, discontinue BENICAR, BENICAR HCT, AZOR, or TRIBENZOR as soon as possible

Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. See WARNINGS AND PRECAUTIONS: Fetal Toxicity

LIMITATIONS OF USE

TRIBENZOR is not indicated for initial therapy.

CONTRAINDICATIONS

Do not co-administer aliskiren with BENICAR, BENICAR HCT, AZOR, or TRIBENZOR in patients with diabetes.

BENICAR HCT and TRIBENZOR are contraindicated in patients with anuria, and in patients with hypersensitivity to any component of BENICAR HCT or TRIBENZOR.

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

WARNINGS AND PRECAUTIONS

Morbidity in Infants: Children <1 year of age must not receive BENICAR for hypertension. Safety and effectiveness of AZOR, BENICAR HCT or TRIBENZOR have not been established in pediatric patients.

Fetal Toxicity: BENICAR, BENICAR HCT, AZOR, and TRIBENZOR are **Pregnancy Category D**. (See Boxed **WARNING** regarding Fetal Toxicity).

Hypotension in Volume- or Salt-Depleted Patients: In patients with an activated reninangiotensin system, such as volume- and/or salt-depleted patients (eg, those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of treatment with BENICAR, BENICAR HCT, AZOR, or TRIBENZOR. Observe for sign and symptoms of hypotension, and fluid and electrolyte imbalances.

Correct volume-depletion prior to administration of BENICAR HCT. Correct volume or salt depletion prior to administration of TRIBENZOR.

Impaired Renal Function: Patients whose renal function may depend in part upon the activity of the renin-angiotensin-aldosterone system (eg. patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure, or volume depletion), may be at particular risk of developing acute renal failure on BENICAR, BENICAR HCT, AZOR and TRIBENZOR. Monitor renal function periodically in these patients. Monitor potassium as directed for BENICAR HCT and TRIBENZOR. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function on BENICAR, BENICAR HCT, AZOR and TRIBENZOR.

Safety and effectiveness of BENICAR HCT in patients with severe renal impairment (creatinine clearance (CrCl) ≤ 30 mL/min) have not been established. Avoid use of TRIBENZOR in patients with severely impaired renal function (CrCl ≤ 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, and similar results may be expected with olmesartan products.

Sprue-like Enteropathy: Severe, chronic diarrhea with substantial weight loss has been reported in patients taking olmesartan months to years after drug initiation. Intestinal biopsies of patients often demonstrated villous atrophy. If a patient develops these symptoms during treatment with olmesartan, exclude other etiologies. Consider discontinuation of BENICAR, BENICAR HCT, AZOR, or TRIBENZOR in cases where no other etiology is identified.

Hepatic Impairment: Initial therapy with AZOR or TRIBENZOR is not recommended in hepatically impaired patients. In patients with severe hepatic impairment, exercise caution with AZOR and avoid use of TRIBENZOR. Thiazides (a component in BENICAR HCT and TRIBENZOR) may cause minor alterations of fluid and electrolyte balance that may precipitate hepatic coma in patients with impaired hepatic function or progressive liver disease.

Electrolyte and Metabolic Imbalances: BENICAR, BENICAR HCT, AZOR, and TRIBENZOR contain olmesartan, a drug that inhibits the renin-angiotensin system (RAS). Drugs that inhibit the RAS can cause hyperkalemia. Observe for signs of fluid or electrolyte imbalance and monitor serum electrolytes periodically. BENICAR HCT and TRIBENZOR contain hydrochlorothiazide which can cause hypokalemia, hyponatremia, and hypomagnesemia. Hypomagnesemia can result in hypokalemia which may be difficult to treat despite potassium repletion. Hydrochlorothiazide (HCTZ) (a component of BENICAR HCT and TRIBENZOR) may alter glucose tolerance, raise serum levels of cholesterol and triglycerides, cause elevations of serum calcium, and hyperuricemia or frank gout may occur.

Postsympathectomy Patients: The antihypertensive effects of the drug may be enhanced in the post-sympathectomy patient**.**

Hypersensitivity Reaction: Hypersensitivity reactions to HCTZ (a component in BENICAR HCT and TRIBENZOR) may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history.

Systemic Lupus Erythematosus: Thiazides (a component in BENICAR HCT and TRIBENZOR) have been reported to cause exacerbation or activation of systemic lupus erythematosus.

Acute Myopia and Secondary Angle-Closure Glaucoma: Thiazides can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure glaucoma. Discontinue HCTZ (a component in BENICAR HCT and TRIBENZOR) as rapidly as possible in these patients.

Increased Angina and/or Myocardial Infarction: Patients taking AZOR or TRIBENZOR, 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 dose increase.

Laboratory Tests: Lab abnormalities may include increased blood creatinine levels and hyperkalemia (olmesartan medoxomil), and increased cholesterol and triglyceride levels (HCTZ).

DRUG INTERACTIONS

Non-Steroidal Anti-Inflammatory Agents: Concurrent administration of non-steroidal anti-inflammatory drugs (NSAIDs) may lead to increased risk of renal impairment (including possible acute renal failure) and loss of antihypertensive effect of BENICAR, BENICAR HCT, AZOR, and TRIBENZOR. Monitor renal function periodically in patients receiving olmesartan medoxomil and NSAID therapy.

Dual Blockade of the Renin-Angiotensin System (RAS): Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Most patients receiving the combination of two RAS inhibitors do not obtain any additional benefit compared to monotherapy. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function, and electrolytes in patients on BENICAR, BENICAR HCT, AZOR, or TRIBENZOR and other agents that affect the RAS. Do not co-administer aliskiren with BENICAR, BENICAR HCT, AZOR, or TRIBENZOR in patients with diabetes. Avoid use of aliskiren with BENICAR, BENICAR HCT, AZOR, or TRIBENZOR in patients with renal impairment (GFR < 60 mL/min).

Concurrent Use with Colesevelam Hydrochloride: Concurrent administration of colesevelam hydrochloride with BENICAR, BENICAR HCT, AZOR, or TRIBENZOR reduces the systemic exposure and peak plasma concentration of olmesartan. Consider administering olmesartan at least 4 hours before the colesevelam hydrochloride dose.

Effect of Amlodipine on Simvastatin: Due to increased exposure to simvastatin, when coadministered with amlodipine (a component in AZOR and TRIBENZOR), do not exceed doses of greater than 20 mg daily of simvastatin.

Lithium: Increases in serum lithium concentrations and lithium toxicity have been reported with concomitant use of olmesartan or thiazide diuretics. Monitor lithium levels in patients receiving BENICAR, BENICAR HCT, AZOR, or TRIBENZOR and lithium.

Immunosuppressants: Amlodipine (a component in AZOR and TRIBENZOR) may increase the systemic exposure of cyclosporine or tacrolimus when co-administered. Frequent monitoring of trough blood levels of cyclosporine and tacrolimus is recommended and adjust the dose when appropriate.

CYP3A inhibitors: Co-administration of amlodipine (a component in AZOR and TRIBENZOR) with CYP3A inhibitors (moderate and strong) results in increased systemic exposure to amlodipine and may require dose reduction. Monitor for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A inhibitors to determine the need for dose adjustment

CYP3A inducers: No information is available on the quantitative effects of CYP3A inducers on amlodipine (a component in AZOR and TRIBENZOR). Blood pressure should be closely monitored when amlodipine is co-administered with CYP3A inducers.

Antidiabetic drugs: Dosage adjustment of the antidiabetic drug may be required due to hydrochlorothiazide (a component of BENICAR HCT and TRIBENZOR).

Cholestyramine and colestipol: Reduced absorption of thiazides. Consider administering BENICAR HCT 4 hours before or 4-6 hours after the administration of the resin.

Corticosteroids, ACTH: Intensified electrolyte depletion, particularly hypokalemia due to hydrochlorothiazide (a component of BENICAR HCT and TRIBENZOR).

ADVERSE REACTIONS

BENICAR: The only adverse reaction that occurred in >1% of patients treated with BENICAR and more frequently than placebo was dizziness (3% vs 1%).

BENICAR HCT: Adverse reactions reported in >2% of patients taking BENICAR HCT and more frequently than placebo included nausea (3% vs 0%), hyperuricemia (4% vs 2%), dizziness (9% vs 2%), and upper respiratory tract infection (7% vs 0%).

AZOR: The most common adverse reaction (incidence ≥3%) in patients treated with AZOR was edema.

TRIBENZOR: The most frequently reported adverse reaction was dizziness (5.8% to 8.9%). The other most frequent adverse reactions occurring in ≥2% of patients treated

TRIBENZOR: The most frequently reported adverse reaction was dizziness (5.8% to 8.9%). The other most frequent adverse reactions occurring in ≥2% of patients treated with TRIBENZOR were 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%).

USE IN SPECIFIC PATIENT POPULATIONS

Nursing Mothers: Avoid use while nursing; discontinue either nursing or the drug.

Please see Full Prescribing Information for BENICAR, BENICAR HCT, AZOR, and TRIBENZOR.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around

the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with a Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Basking Ridge, 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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