Better Health, Brighter Future

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News Release

Takeda Responds to Ruling in Diabetes Drug Case
Expresses Continued Confidence in ACTOS

Deerfield, Ill., October 27, 2014, and Osaka, Japan, October 28, 2014–Takeda Pharmaceutical Company Limited ("Takeda") and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc. today announced that Judge Rebecca Doherty reduced the punitive damage award in Terrence Allen, et al. v. Takeda Pharmaceuticals North America, Inc., et al. (U.S. Dist. Ct., W. Dist. of Louisiana, Case No. 12-0064) from $6 billion against Takeda and $3 billion against Eli Lilly to $27.65 million against Takeda and $9.22 million against Eli Lilly. Compensatory damages were previously reduced from $1.475 million to $1.27 million. The court entered a judgment reflecting these amounts.

"We view the substantially reduced punitive damage award as a step in the right direction, but we believe a damage award of any amount is not justified based on the evidence presented in this trial and we will appeal," said Kenneth D. Greisman, senior vice president and general counsel, Takeda Pharmaceuticals U.S.A., Inc. "Patient safety is a critical priority for Takeda. There is no credible scientific evidence that establishes a causal link between ACTOS and this disease."

Takeda has prevailed in five of the first six ACTOS cases tried in state courts thus far. The Allen case is the only case to reach trial in the multidistrict litigation pending in the federal courts and the only case to result in a punitive damage award.

Indication for ACTOS

ACTOS (pioglitazone) is a prescription medicine used with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes. ACTOS is not for the treatment of type 1 "juvenile" diabetes or diabetic ketoacidosis (increased ketones in blood or urine).

Important Safety Information

WARNING: HEART FAILURE

ACTOS can cause or worsen heart failure. ACTOS can cause the body to keep extra fluid (fluid retention), which leads to swelling (edema) and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure. Heart failure means the heart does not pump blood well enough. Patients should not take ACTOS if they have severe heart failure. If patients have heart failure with symptoms such as shortness of breath or swelling, even if these symptoms are not severe, ACTOS may not be right for them. Patients should call their doctor right away if they experience swelling or fluid retention (especially in the ankles or legs), shortness of breath or trouble breathing (especially when lying down), an unusually fast increase in weight, or unusual tiredness.

ACTOS may not be right for everyone. Serious side effects may happen to people taking ACTOS.

Patients should not take ACTOS if they are allergic to any of its ingredients.

ACTOS may cause liver problems. Patients should call their doctor right away if they experience nausea, vomiting, stomach pain, unusual or unexplained tiredness, loss of appetite, dark urine, or yellowing of the skin or eyes, as these could be symptoms of liver damage.

Women are at higher risk of having broken bones (fractures) while taking ACTOS.

There may be an increased chance of having bladder cancer when patients take ACTOS. Patients should not take ACTOS if they are receiving treatment for bladder cancer. Patients should tell their doctor right away if they have blood or a red color in the urine, have an increased need to urinate, or have pain while they urinate, as these may be symptoms of bladder cancer.

When taking ACTOS with insulin or other anti-diabetic medications (especially sulfonylureas), hypoglycemia (low blood sugar) may occur. Lightheadedness, shakiness, dizziness, or hunger may mean that a patient’s blood sugar is too low. Patients should talk to their doctor if low blood sugar is a problem for them.

Some patients have experienced visual changes while taking ACTOS. If patients experience vision problems, patients should consult their doctor immediately. Patients should have their eyes checked regularly.

If a woman is of childbearing age, but does not have monthly periods, she should talk to her doctor before taking ACTOS, as it could increase her chance of becoming pregnant.

It is not known if ACTOS can harm an unborn or nursing baby. Patients should talk to their doctor if they are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed.

Adverse Reactions

The most common side effects (>5%) of ACTOS include cold-like symptoms, headache, sinus infection, muscle pain, and sore throat.

Drug Interactions

Patients should tell their doctor about all the medicines, vitamins, and supplements they take. ACTOS and some other medicines can affect each other. Patients may need to have their dose of ACTOS or certain other medicines changed.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see the accompanying Complete Prescribing Information and Medication Guide for ACTOS.

About Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. are subsidiaries of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. The respective companies currently market oral diabetes, insomnia, rheumatology, and gastroenterology treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for metabolic and cardiovascular disease, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit www.takeda.us.

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

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