

News Release

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Takeda Agrees to Settle Actos Product Liability Lawsuits and Claims; Takeda Stresses Continued Commitment to Actos

Deerfield, Ill. U.S., April 28, and Osaka, Japan, April 29, 2015 – Takeda Pharmaceutical Company Limited and its wholly-owned subsidiary, Takeda Pharmaceuticals U.S.A., Inc., today announced that they have reached agreement expected to resolve the vast majority of ACTOS (pioglitazone) product liability lawsuits pending against Takeda in the U.S. Takeda will take a \$2.7 billion charge against earnings in the fourth quarter of fiscal year 2014 to cover the settlement and the costs associated with defending remaining cases and for other related litigation. The settlement will become effective if 95 percent of current litigants and claimants opt into the settlement. Once that threshold is achieved, Takeda will pay \$2.37 billion into a settlement fund. However, that figure will rise to \$2.4 billion if 97 percent or more of the current litigants and claimants opt to participate in the settlement.

Takeda believes that the claims made in this litigation are without merit, and does not admit liability. Takeda believes the company acted responsibly with regard to ACTOS, and that ACTOS has a positive benefit/risk profile for the treatment of type 2 diabetes. Takeda's decision to settle does not change the company's continued commitment to ACTOS. ACTOS continues to be available as a treatment option in the U.S., Japan and other countries. Pioglitazone has been approved for use in 95 countries, including the U.S., Japan, several in Europe, Australia, Brazil, Canada and Russia, to highlight a few.

Takeda Pharmaceutical Company Limited

The settlement will reduce financial uncertainties for the company and provides a significant degree of assurance toward resolving a high percentage of the Actos product liability claims. The settlement allows the company to fully focus on developing innovative medicines for patients around the world.

Under the settlement, current litigants and claimants who meet prescribed criteria would receive payouts from the fund. The settlement will not affect Takeda's ability to pay dividends.

Takeda stands behind the substantial data that confirm a positive benefit/risk profile for ACTOS, which includes more than 14 years of clinical and patient experience with the product.

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 <u>www.fda.gov/medwatch</u> 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 Development Center Americas, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, 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 <u>www.takeda.us</u>.

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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