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**FDA Approves ACTOplus met<sup>®</sup> XR (pioglitazone HCl and metformin HCl extended-release) Tablets for the Treatment of Type 2 Diabetes**

*First and only oral antidiabetic fixed-dose combination medication approved with the extended-release form of metformin*

**Deerfield, Ill., (May 13, 2009) and Osaka, Japan (May 14, 2009)** – Takeda Pharmaceutical Company Limited and its wholly-owned subsidiary, Takeda Pharmaceuticals North America, Inc., today announced that the U.S. Food and Drug Administration (FDA) approved an extended-release version of the combination medication ACTOplus met<sup>®</sup> (pioglitazone HCl and metformin HCl) as an adjunct to diet and exercise for the treatment of type 2 diabetes. ACTOplus met<sup>®</sup> XR is the first and only prescription oral antidiabetic fixed-dose combination medication available with the extended-release form of metformin to help improve glycemic control in a convenient, once-daily dosing option. ACTOplus met XR is indicated for adults with type 2 diabetes who are already treated with ACTOS<sup>®</sup> (pioglitazone HCl) and metformin or who have inadequate glycemic control on ACTOS or metformin alone.

ACTOplus met XR combines ACTOS and metformin, two widely used medications in a single tablet. ACTOS directly targets insulin resistance, a condition in which the body does not efficiently use the insulin it produces. Metformin acts by reducing the amount of glucose produced by the liver. These medications work in combination to help patients with type 2 diabetes manage their blood glucose levels.

Extended-release metformin, one of the active ingredients in ACTOplus met XR, was developed by Watson Laboratories, a subsidiary of Watson Pharmaceuticals, Inc. and licensed to Takeda Pharmaceutical Company Limited. Takeda expects ACTOplus met XR to be available later this calendar year.

**About Type 2 Diabetes**

Diabetes has reached epidemic proportions in the United States. Almost 24 million people currently live with diabetes and, of these, 5.7 million are unaware that they have it. Type 2 diabetes is a progressive and chronic condition and requires continued monitoring by a patient and physician, and in addition to diet and exercise, patients may need to take multiple medications at any time in order to help maintain glucose control. In 2007, the world is estimated to have spent at least \$232 billion to treat and prevent diabetes and its complications. By 2025, this estimate will exceed \$302.5 billion.

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**Important Safety Information about ACTOplus met<sup>®</sup> (pioglitazone HCl and metformin HCl) and ACTOplus met<sup>®</sup> XR (pioglitazone HCl and extended-release metformin HCl)**

ACTOplus met and ACTOplus met XR are not for everyone. Certain patients with heart failure should not start taking ACTOplus met and ACTOplus met XR. ACTOplus met and ACTOplus met XR can cause or worsen congestive heart failure. Talk to your doctor immediately if you experience rapid weight gain, fluid retention (swelling), or shortness of breath.

A small number of people who have taken metformin, a component of ACTOplus met and ACTOplus met XR, have developed a rare, serious condition called lactic acidosis. Lactic acidosis, a buildup of lactic acid in the blood, can be fatal in about half the cases. Because lactic acidosis occurs most frequently in people with kidney problems, ACTOplus met and ACTOplus met XR should not be used in people with kidney disease or in people 80 years of age and older whose kidneys do not work properly. ACTOplus met and ACTOplus met XR should not be taken by people with metabolic acidosis, or with hypersensitivity to pioglitazone, metformin, or any other component of ACTOplus met and ACTOplus met XR. ACTOplus met and ACTOplus met XR should not be taken by people who drink excessive amounts of alcohol. ACTOplus met and ACTOplus met XR should be discontinued in patients with severe infection or in patients undergoing X-ray studies using intravenous contrast dye. Talk to your health professional before discontinuing any medications.

Your health professional should perform a blood test to check for liver problems before you start ACTOplus met and ACTOplus met XR and periodically thereafter. Do not take ACTOplus met and ACTOplus met XR if you have active liver disease. Talk to your doctor immediately if you experience nausea, vomiting, stomach pain, tiredness, loss of appetite, dark urine, or yellowing of the skin. If you are of childbearing age, talk to your doctor before taking ACTOplus met and ACTOplus met XR, as they could increase your chance of becoming pregnant. Some people, particularly women, are at higher risk of having bone fractures while taking ACTOplus met and ACTOplus met XR. Patients with diabetes should have regular eye exams. If you experience vision problems, consult your doctor immediately. Very rarely, some patients have experienced visual changes while taking pioglitazone, a component of ACTOplus met and ACTOplus met XR.

Safety and effectiveness of ACTOplus met and ACTOplus met XR in pediatric patients have not been established. Use in pediatric patients is not recommended for the treatment of diabetes due to lack of long-term safety data. ACTOplus met XR must be swallowed whole and not chewed, cut, or crushed.

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ACTOplus met, ACTOplus met XR, or any other antidiabetic drug.

Please visit the Takeda Pharmaceuticals North America, Inc. Web site at [www.tpna.com](http://www.tpna.com) for Complete Prescribing Information including boxed warnings and a Medication Guide.

**Takeda Pharmaceutical Company Limited**

Located in Osaka, Japan, Takeda (TSE:4502) is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products.

**Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc.**

Based in Deerfield, Ill., Takeda Pharmaceuticals North America, 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 diabetes, cardiovascular disease, oncology, gastroenterology, neurology and other conditions. Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. To learn more about these Takeda companies, visit [www.tpna.com](http://www.tpna.com).

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