Pfizer Logo

Pfizer Announces European Union Approval Of A New Form Of Lipitor (atorvastatin) For Use In Children

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EU Regulation Allows Pfizer to Apply to Extend Lipitor Patent Protection by Six Months in Certain EU Countries

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced it has received European Commission approval of a new chewable form of Lipitor (atorvastatin calcium) suitable for use in children aged 10 or older with high levels of LDL (“bad”) cholesterol and high triglycerides due to the inherited disorder familial hypercholesterolemia and other primary causes, which can increase the risk of heart disease and premature death. This pediatric indication has also been approved for the currently available tablet form of Lipitor.

The Decision to approve the use of atorvastatin in these pediatric patients in Europe is based on the results of a pediatric investigation plan (PIP) filed by Pfizer with the European Medicines Agency (EMA) in November 2009. Investigations into pediatric use are required by recent European pediatric regulations1 in an effort to encourage pharmaceutical companies to increase understanding of the use of medicines in children. Pfizer hopes to improve treatment options for such pediatric patients, reflecting its ongoing support for patients at risk of cardiovascular disease.

To support the investments necessary to conduct clinical trials in children, the EU created certain incentives, including the availability of a six-month extension to an existing patent extension, also known as a supplementary protection certificate (SPC). As previously announced in November 2009, Pfizer intends to apply for the additional six months of patent protection in European countries where it has an SPC. A country-by-country process will be required to secure this patent term extension.

Based on the results of Pfizer-sponsored trials, in March, the EMA’s Committee for Medicinal Products for Human Use (CHMP) recommended that a pediatric-appropriate formulation of Lipitor (chewable tablets) be approved for the treatment of hypercholesterolaemia in adolescents and children aged 10 years or older, and the approval of this indication for the currently available presentations of Lipitor (film-coated tablets). The European Commission Decision formalizes these recommendations, which must now be implemented in all EU member states.

As a result of an earlier pediatric clinical development program, Lipitor has been approved for use in children (aged 10 to 17 years) with heterozygous familial hypercholesterolemia in the United States since 2002.

Important U.S. Prescribing Information

LIPITOR is a prescription medicine that is used along with a low-fat diet, and when diet and exercise are not enough. It lowers the LDL ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL ("good" cholesterol) as well. LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest

pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking, or high blood pressure.

LIPITOR is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant or may become pregnant.

Patients taking LIPITOR should tell their doctor if they feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Patients should tell their doctor about all medications they take. This may help avoid serious drug interactions. Doctors should do blood tests to check your liver function before and during treatment and may adjust the dose. Common side effects are diarrhea, upset stomach, muscle and joint pain, and changes in some blood tests.

For additional product information, visit www.Lipitor.com.

Pfizer Inc: Working Together for a Healthier World™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE:

The information contained in this release is as of July 6, 2010. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties. These include, among other things, the Company's ability to satisfy the procedural requirements of the EU Paediatric Medicines Regulation relating to the application for the additional six months of patent/SPC protection in certain EU countries.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and in its reports on Form 10-Q and Form 8-K.

1. Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, amended by Regulation (EC) No 1902/2006.

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