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Pfizer Submits New Pediatric Data For Lipitor® (Atorvastatin) To The European Medicines Agency (EMEA)

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Filing Follows EMEA's Conclusion that Pfizer's Program Studying the Use of Lipitor in Children with High Cholesterol is in Compliance with its Requirements

(BUSINESS WIRE)--Pfizer Inc (NYSE:PFE) announced it has submitted pediatric data for Lipitor® (atorvastatin) to the European Medicines Agency (EMEA). Pfizer has also developed a new chewable form of Lipitor, including a pediatric-appropriate 5 mg dose, which is part of this submission.

Approximately one in 500 people suffer from an inherited disorder, called Familial Hypercholesterolemia (FH), which causes high levels of LDL-cholesterol ("bad" cholesterol) and an increased risk of heart disease. Pfizer hopes that additional scientific data about the use of atorvastatin in children with FH will help improve diagnosis and treatment of the condition.

Pfizer's data submission reflects a European Union (EU) initiative encouraging research, development and availability of medicines for children. All authorized medicines undergo extensive testing in both laboratories and clinical trials prior to their approval. However, there is often limited information available about pediatric use. One 2005 study found that more than half of all medicines in Europe have not been tested and authorized for use in children.

In 2007, the EU enacted a new Regulation requiring pharmaceutical companies to research their medicines for use by children. The requirements cover new medicines, and existing ones under certain circumstances. In 2008, the EMEA's Paediatric Committee approved Pfizer's pediatric investigation plan to study the use of Lipitor in children aged 6 to under 18. This week, the Committee concluded that Pfizer's pediatric atorvastatin program has been implemented in compliance with its requirements.

To encourage companies to make the investments necessary to conduct these trials, the EU also created certain incentives, including the availability of a six-month extension to an existing patent extension, also known as a supplementary protection certificate (SPC). If Pfizer fulfils all further requirements of the EU Paediatric Medicines Regulation, Pfizer will be eligible and intends to apply for an additional six months of patent/SPC protection for Lipitor in certain EU countries.

Pfizer is committed to improving the lives of all adults and children at risk of cardiovascular disease and will continue to work closely with the EMEA and other regulatory authorities to help address areas of unmet medical need and reduce health inequalities. Lipitor has been approved for use in children (aged 10 to 17 years old) 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. 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.

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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 November 18, 2009. 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 regarding a potential indication in the EU for Lipitor for use by children and a proposed new chewable form of Lipitor in a 5 mg dose, which are under review by the European Medicines Agency (EMEA), as well as the Company's possible eligibility to apply for an additional six months of patent/SPC protection for Lipitor in the EU. Such risks and uncertainties include, among other things, the uncertainties inherent in clinical trials; whether and when the EMEA will approve this indication and this proposed new form and its decisions regarding labeling and other matters that could affect the availability or commercial potential of this indication and this proposed new form; the Company's ability to satisfy the requirements of the EU Paediatric Medicines Regulation necessary to be eligible to apply for the additional six months of patent/SPC protection; as well as competitive developments.

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, 2008 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 pediatric use, amended by Regulation (EC) No 1902/2006.

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