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[Updated on December 13th, 2007] Statement by Merck & Co., Inc., Regarding the Fracture Intervention Trial (FIT) with FOSAMAX® (alendronate sodium) and Incidence of Atrial Fibrillation

WHITEHOUSE STATION, N.J., May 2, 2007 - Merck & Co., Inc. responds to the publication in the New England Journal of Medicine (New Engl J Med, May 3, 2007) of the HORIZON Trial and a Letter to the Editor referencing adverse events of atrial fibrillation from the Fracture Intervention Trial (FIT):

FIT was the largest clinical study ever conducted to evaluate the effect of FOSAMAX® (alendronate sodium) on the risk of osteoporotic fracture. It was conducted over a period of five years, concluding in 1997. The overall risk of atrial fibrillation adverse events in FIT was similar between FOSAMAX and placebo (FOSAMAX (2.5%) and placebo (2.2%); $p=0.42$). Looking only at atrial fibrillation adverse events that were serious, the incidence was not statistically significantly different with FOSAMAX compared to placebo although it was numerically higher (FOSAMAX (1.5%) and placebo (1.0%); $p=0.07$).

Atrial fibrillation adverse experiences were collected throughout the duration of FIT and verified by an independent physician who was "blinded" to patient treatment. The study was also monitored by a Data Safety Monitoring Board (DSMB) which at no time found cause to stop the study due to a safety data finding.

At the end of the study, which was almost 10 years ago, the external, independent study investigators and Merck prepared analyses of all atrial fibrillation adverse experiences from FIT. Based upon these analyses, as noted in the NEJM letter, a true association between atrial fibrillation and treatment with FOSAMAX was considered unlikely by both the independent study investigators and Merck.

Merck reported these findings to FDA and other regulatory agencies worldwide after the conclusion of FIT in accordance with domestic and international reporting regulations and safety guidelines.

The finding that serious adverse experiences of atrial fibrillation were increased in patients treated with zoledronic acid in the HORIZON trial was first reported six months ago at the American Society for Bone and Mineral Research Annual Meeting in September 2006. Merck has since re-reviewed the data concerning atrial fibrillation adverse experiences in 28 other placebo-controlled trials in which reports of atrial fibrillation adverse experiences were not subject to independent adjudication. In this preliminary analysis that combined data from these other trials, the observed incidence of atrial fibrillation based upon counts of adverse experiences (whether all adverse experiences or only those that were reported as serious) was similar in patients receiving FOSAMAX compared to placebo.

About the FIT Study

FIT was a placebo-controlled, double-blind study that enrolled 6459 postmenopausal women who were followed for up to four and one-half years. FOSAMAX was dosed at 5 mg daily during the first two years of the study and 10 mg daily thereafter.

During FIT, atrial fibrillation adverse experience reports were collected by external study investigators and verified by an independent physician who was "blinded" to a patient's treatment. Adverse events in the FIT study were reported as either serious or non-serious based on reporting regulations and conventions.

Consistent with Merck clinical practice in large, long-term trials, an external Data and Safety Monitoring Board (DSMB) conducted unblinded interim safety analyses through the duration of the study. The DSMB found no cause to stop the study due to a safety data finding at any time. The data from FIT are summarized in the table below as counts of atrial fibrillation adverse experiences.

Comparisons of FOSAMAX vs. placebo in FIT

		Atrial Fibrillation AE, n (%)	
		Placebo	FOSAMAX
		N=3223	N=3236
Fracture Intervention Trial*	All	71 (2.2)	81 (2.5)†
	Serious^^	31 (1.0)	47 (1.5)‡

* FOSAMAX 5 mg daily for 2 years, then 10 mg daily

^^ Serious AEs, as defined by regulatory standards, include those that result in hospitalization, are life-threatening, or result in disability or death.

† p=0.421

‡ p=0.068

Other Studies

Since the completion of FIT, atrial fibrillation adverse experiences in our clinical studies and post-marketing reports have been recorded and summarized in the clinical reports of these studies and have been reported to the FDA and other regulatory agencies worldwide in accordance with domestic and international reporting regulations and safety guidelines.

Merck has also re-reviewed the data concerning atrial fibrillation adverse experiences in 28 other placebo-controlled studies (in addition to FIT). We also re-reviewed data from two additional studies that compared daily FOSAMAX 5 or 10 mg to 35 or 70 mg once-weekly. A preliminary analysis that combined data from these studies is summarized in the tables below as counts of atrial fibrillation adverse experiences.

These trials had a duration of at least 3 months, studied doses approved for the prevention or treatment of osteoporosis, and included patients treated with oral FOSAMAX in 21 placebo-controlled trials of FOSAMAX 5 and/or 10 mg daily (duration from 3 months to 4 years), 7 placebo-controlled trials of FOSAMAX 70 mg once-weekly (duration from 3 months to 2 years), and 2 trials comparing daily FOSAMAX 5 or 10 mg to 35 or 70 mg once-weekly (duration of 2 years). These trials differed from FIT in several respects: the study population in these trials was generally younger than that in FIT, and the trials were mostly of a shorter duration. Moreover, these were trials in which reports of atrial fibrillation adverse experiences were made by the physicians at each study site and were not subject to

independent adjudication.

Data from trials of FOSAMAX used either intravenously or in higher or lower oral doses were not included; also excluded were comparisons of FOSAMAX only to other active drugs.

As with all of its medicines, Merck regularly monitors adverse experiences with FOSAMAX in its clinical trials and post-marketing events and reports these events to regulatory agencies worldwide in accordance with domestic and international reporting regulations and safety guidelines.

FOSAMAX has been studied in over 13,000 patients treated with FOSAMAX and has been on the market for over 12 years during which time over 150 million prescriptions have been written in the US alone.

Comparisons of FOSAMAX vs. placebo in other studies

		Atrial Fibrillation AE, n (%)	
		Placebo	FOSAMAX
		N=3089	N=3921
Other placebo-controlled, daily ^{***^}	All	13 (0.4)	18 (0.4)
	Serious	7 (0.2)	8 (0.2)
		N=1071	N=1280
Placebo-controlled, weekly ^{***}	All	2 (0.2)	3 (0.2)
	Serious	1 (0.1)	0 (0.0)

** 21 trials; FOSAMAX 5 or 10 mg daily, duration from 3 months to 4 years

*** 7 trials; FOSAMAX 70 mg weekly, duration from 3 months to 2 years

[^] Data for non-serious AF AEs from a 428-patient study were not available; no serious AF AEs were reported. This study is not included in the tabulation.

Comparison of FOSAMAX dosing regimens^{****}

	Atrial Fibrillation AE, n (%)	
	5 mg Daily N=361	35 mg Weekly N=362
All	1 (0.3)	0 (0.0)
Serious	1 (0.3)	0 (0.0)

	Atrial Fibrillation AE, n (%)		
	10 mg Daily N=370	35 mg 2x/wk N=369	70 mg Weekly N=519
All	0 (0.0)	1 (0.3)	4 (0.8)
Serious	0 (0.0)	1 (0.3)	2 (0.4)

**** 2 trials; duration of 2 years

FDA Early Communication

On October 1, 2007, the FDA issued an "Early Communication of an Ongoing Safety Review" of bisphosphonates including alendronate (Fosamax, Fosamax Plus D), etidronate (Didronel), ibandronate (Boniva), pamidronate (Aredia), risedronate (Actonel, Actonel with Calcium), tiludronate (Skelid), and zoledronic acid (Reclast, Zometa). This communication is posted on the FDA web site at

http://www.fda.gov/cder/drug/early_comm/bisphosphonates.htm

Important information about FOSAMAX

FOSAMAX, like other bisphosphonate containing products, should be used with caution in people with certain stomach or digestive problems. FOSAMAX should not be used if the patient has certain disorders of the esophagus that delay emptying or if the patient is unable to stand or sit upright for at least 30 minutes. In addition, FOSAMAX should not be used in patients with severe kidney disease or low levels of calcium in their blood, in patients who are allergic to FOSAMAX or in patients who are pregnant or nursing. Patients who have difficulty swallowing liquids should not take FOSAMAX oral solution.

Some patients may develop severe digestive reactions including irritation, inflammation or ulceration of the esophagus. The risk of severe esophageal experiences appears to be greater in patients who fail to follow dosing instructions (see prescribing information for more details). Patients who experience new or worsening heartburn, difficulty or pain when swallowing or chest pain should stop taking the drug and call their doctor right away. Patients who develop severe bone, joint and/or muscle pain at any time should contact their doctor.

The standard dosing regimen for FOSAMAX includes swallowing the tablet with six to eight ounces of plain water the first thing upon arising for the day and at least 30 minutes before the first food, beverage or medication of the day. After swallowing FOSAMAX, patients should not lie down for at least 30 minutes and not until after consuming their first food of the day. Patients should not chew or suck on a tablet of FOSAMAX.

For more information on products containing FOSAMAX, please see and read the prescribing information and patient package insert which are available at www.fosamax.com.

FORWARD-LOOKING STATEMENT

This statement contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this statement should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.