Merck Favorably Resolves FOSAMAX® (alendronate sodium) ONJ litigation

Terms:
Company Statements Fosamax Merck MRK

Published Date and Time:
12/9/13 3:16 pm EST

News Organization Location:
WHITEHOUSE STATION, N.J

Merck has agreed in principle to resolve all of the existing product liability cases in the U.S. alleging that FOSAMAX caused osteonecrosis of the jaw (ONJ). The settlement agreement does not resolve cases alleging femur fractures. We are pleased with this resolution of the ONJ litigation, and we continue to be committed to the vigorous defense of these cases. Above all, we will continue to always act in the best interest of patients. We remain confident in the efficacy and safety profile of FOSAMAX, which was developed and studied carefully by dedicated Merck scientists.

Since the litigation began in 2005, Merck has won five of the seven ONJ cases that have been tried to verdict. The claims of approximately 1200 other plaintiffs remain pending. Under this agreement, these claims will be resolved for a total of $27.7 million, provided that various contingencies and requirements are met, including a 100 percent participation rate and sufficient evidence that claimants satisfy specific eligibility requirements.

About FOSAMAX (alendronate sodium)

FOSAMAX is indicated for the treatment and prevention of osteoporosis in postmenopausal women. The optimal duration of use has not been determined. The safety and effectiveness of FOSAMAX for the treatment of osteoporosis are based on clinical data of four years’ duration. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low risk for fracture should be considered for drug discontinuation after three to five years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.

FOSAMAX should not be used in patients who have certain disorders of the esophagus that delay emptying, who are unable to stand or sit upright for at least 30 minutes, who have low levels of calcium in their blood, or in patients who are allergic to FOSAMAX. Some patients may develop severe digestive reactions, including irritation, inflammation, or ulceration of the esophagus. Dosing instructions should be followed, and 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. Osteonecrosis of the jaw (ONJ), generally associated with tooth extraction and/or local infection, with delayed healing, has been reported in patients taking bisphosphonates, including FOSAMAX. The risk of ONJ may increase with duration of exposure to bisphosphonates. Atypical femur fractures have been reported in patients taking bisphosphonates.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com.

Forward-Looking Statement

This statement includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the
forward-looking statements can be found in Merck’s 2012 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

The Prescribing information and Medication Guide for FOSAMAX® (alendronate sodium) are attached and are available at:

FOSAMAX® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

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Language:
English