Merck Voluntarily Recalls All Lots of LIPTRUZET™ in the United States From Wholesalers Due to Packaging Defects

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Merck (NYSE: MRK), known as MSD outside the United States and Canada, is voluntarily recalling all lots of LIPTRUZET™ (ezetimibe and atorvastatin) 10/10 mg, 10/20 mg, 10/40 mg and 10/80 mg tablets in the United States, including Puerto Rico, due to packaging defects.

Merck is recalling from wholesalers all lots of LIPTRUZET that have been distributed since the product was introduced in May 2013. Some of the outer laminate foil pouches may allow in air and moisture, which could potentially decrease the effectiveness or change the characteristics of the product. The likelihood of the packaging defects decreasing the effectiveness of LIPTRUZET on a patient’s lipid profile or negatively impacting the safety of the product is remote. The decision to recall LIPTRUZET was not based on any reported adverse experiences or product quality complaints.

The recall will deplete all available supply in the U.S., and stock-outs are expected. The two active ingredients remain available: ZETIA® (ezetimibe), from Merck, and atorvastatin is available as a generic from multiple manufacturers. The recall does not affect any other products manufactured by Merck.

Merck is working with the U.S. Food and Drug Administration (FDA) on this recall. Merck is informing wholesalers in the United States. The medicine is not being recalled from patients or pharmacies. Patients who have questions are encouraged to talk to their health care provider, and to not stop therapy without first speaking with their physician. Merck is committed to resupplying LIPTRUZET as soon as possible.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Adverse reactions or quality problems also may be reported by contacting Merck at 1-800-672-6372 (Monday to Friday 8 a.m. to 7 p.m. Eastern Time).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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 and connect with us on Twitter, Facebook and YouTube.

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).

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