



## News Release

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### **Merck and Schering-Plough Resolve Previously Disclosed Investigation Under State Consumer Protection Statutes Related to VYTORIN<sup>®</sup> (ezetimibe/simvastatin) and ZETIA<sup>®</sup> (ezetimibe)**

WHITEHOUSE STATION, N.J., and KENILWORTH, N.J., July 15, 2009 – Merck & Co., Inc. and Schering-Plough Corporation and the companies' cholesterol joint venture, Merck/Schering-Plough Pharmaceuticals, today said they have reached a civil settlement with a multistate group of attorneys general representing 35 states and the District of Columbia who investigated whether the companies violated state consumer protection laws in connection with the ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia) clinical trial or by their promotion and marketing of VYTORIN and ZETIA.

As part of the resolution of the multistate investigation, the companies agreed to reimburse the investigative costs of the 35 states and the District of Columbia which totaled \$5.4 million. The settlement agreement does not require the companies to make any other payment, and does not require or include any admission of misconduct or liability by the companies.

In the settlement, the companies agreed to continue to comply with the Food, Drug and Cosmetic Act, the U.S. Food and Drug Administration Amendments Act, and other laws requiring the truthful and non-misleading marketing of pharmaceutical products and made other voluntary assurances of compliance related to the promotion of VYTORIN and ZETIA.

"Today's agreement is consistent with our belief that the companies conducted the ENHANCE trial in good faith and that their promotion of VYTORIN and ZETIA was in compliance with the law," said Bruce N. Kuhlik, executive vice president and general counsel of Merck.

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"Resolving these inquiries for an amount equal to the states' investigative costs is in the interests of all stakeholders," said Thomas J. Sabatino, executive vice president and general counsel of Schering-Plough.

In addition to the District of Columbia, the 35 states participating in the agreement are: Arizona, Arkansas, California, Colorado, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

The companies previously disclosed the multistate investigation in filings with the U.S. Securities and Exchange Commission.

### **Important Information about VYTORIN**

VYTORIN contains simvastatin and ezetimibe. VYTORIN is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol, LDL cholesterol, Apo B<sup>1</sup>, triglycerides and non-HDL cholesterol and to increase HDL cholesterol in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia.

VYTORIN is a prescription medicine and should not be taken by people who are hypersensitive to any of its components. VYTORIN should not be taken by anyone with active liver disease or unexplained persistent elevations of serum transaminases. Women who are of childbearing age (unless highly unlikely to conceive), are nursing or who are pregnant should not take VYTORIN. VYTORIN has not been shown to reduce heart attacks or strokes more than simvastatin alone.

Muscle pain, tenderness or weakness in people taking VYTORIN should be reported to a doctor promptly because these could be signs of a serious side effect. VYTORIN should be discontinued if myopathy is diagnosed or suspected. To help avoid serious side effects, patients should talk to their doctor about medicine or food they should avoid while taking VYTORIN. In three placebo-controlled, 12-week trials, the incidence of consecutive elevations ( $\geq 3$  X ULN) in serum transaminases were 1.7 percent overall for patients treated with VYTORIN and 2.6 percent for patients treated with VYTORIN 10/80 mg. In controlled long-term (48-week) extensions, which included both newly-treated and previously-treated patients, the incidence of consecutive elevations ( $\geq 3$  X ULN) in serum transaminases was 1.8 percent overall and 3.6 percent for patients treated with VYTORIN 10/80 mg. These elevations in transaminases were

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<sup>1</sup> Apo B is the protein compound of lipoproteins, LDL and VLDL, which carry cholesterol in the blood.

generally asymptomatic, not associated with cholestasis and returned to baseline after discontinuation of therapy or with continued treatment. Doctors should perform blood tests before, and periodically during treatment with VYTORIN when clinically indicated to check for liver problems. People taking VYTORIN 10/80 mg should receive an additional liver function test prior to and three months after titration and periodically during the first year.

Due to the unknown effects of increased exposure to ezetimibe (an ingredient in VYTORIN) in patients with moderate or severe hepatic insufficiency, VYTORIN is not recommended in these patients. The safety and effectiveness of VYTORIN with fibrates have not been established; therefore, co-administration with fibrates is not recommended. Caution should be exercised when initiating VYTORIN in patients treated with cyclosporine and in patients with severe renal insufficiency.

VYTORIN has been evaluated for safety in more than 3,800 patients in clinical trials and was generally well tolerated at all doses (10/10 mg, 10/20 mg, 10/40 mg, 10/80 mg). In clinical trials, the most commonly reported side effects, regardless of cause, included headache (6.8 percent), upper respiratory tract infection (3.9 percent), myalgia (3.5 percent), influenza (2.6 percent) and extremity pain (2.3 percent).

VYTORIN is available as tablets containing 10 mg of ezetimibe combined with 10, 20, 40 or 80 mg of simvastatin (VYTORIN 10/10, 10/20, 10/40 or 10/80 mg, respectively).

### **Important Information about ZETIA**

ZETIA, along with diet, is indicated for use either by itself or together with statins or fenofibrate in patients with high cholesterol to reduce LDL cholesterol and total cholesterol when the response to diet and exercise has been inadequate.

ZETIA is a prescription medication and should not be taken by people who are allergic to any of its ingredients. When ZETIA is prescribed with a statin, it should not be taken by women who are nursing or pregnant or who may become pregnant, or by anyone with active liver disease. Statins should not be taken by anyone with these conditions. If you have ever had liver problems or are pregnant or nursing, your doctor will decide if ZETIA is right for you. Your doctor may do blood tests to check your liver before you start taking ZETIA with a statin and during treatment. ZETIA has not been shown to prevent heart disease or heart attacks.

Due to the unknown effects of increased exposure to ZETIA in patients with moderate or severe hepatic insufficiency, ZETIA is not recommended in these patients. In clinical trials, there was no increased incidence of myopathy (muscle pain) or rhabdomyolysis (muscle breakdown) associated with ZETIA; however myopathy and rhabdomyolysis are known adverse

reactions to statins and other lipid-lowering drugs. There are no adequate and well-controlled studies of ZETIA in pregnant women. ZETIA should not be used in pregnant or nursing women unless the benefit outweighs the potential risks.

When ZETIA was co-administered with a statin, consecutive elevations in liver enzymes, more than three times the upper limit of normal, were slightly higher than those with the statin alone (1.3 percent vs. 0.4 percent). These elevations were generally asymptomatic and returned to baseline after discontinuation of therapy or with continued treatment. When ZETIA was co-administered with fenofibrate, consecutive elevations in liver enzymes more than three times the upper limit of normal, were 2.7%, and 4.5% in patients treated with fenofibrate alone. Caution should be exercised when initiating ZETIA in patients treated with cyclosporine, particularly in patients with severe renal insufficiency, due to increased blood levels of ZETIA.

In clinical trials, most frequent side effects for ZETIA alone vs. placebo included: back pain (4.1percent vs. 3.9 percent), arthralgia (3.8 percent vs. 3.4 percent), and fatigue (2.2 percent vs. 1.8 percent); for ZETIA plus statin vs. statin or placebo alone: back pain (4.3 percent vs. 3.7 percent vs. 3.5 percent), abdominal pain (3.5 percent vs. 3.1 percent vs. 2.3 percent), and fatigue (2.8 percent vs. 1.4 percent vs. 1.9 percent).

### **About Merck/Schering-Plough Pharmaceuticals**

Merck/Schering-Plough Pharmaceuticals is a joint venture between Merck & Co., Inc. and Schering-Plough Corporation formed to develop and market in the United States new prescription medicines in cholesterol management. The collaboration includes worldwide markets (excluding Japan). VYTORIN is also marketed as INEGY<sup>®</sup> outside the U.S. ZETIA is marketed outside the U.S. as EZETROL<sup>®</sup>.

### **Merck Forward-looking Statement**

This press release 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 press release 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, 2008, and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

### **Schering-Plough Disclosure Notice**

The information in this press release includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to litigation and investigations concerning VYTORIN and ZETIA<sup>®</sup> (ezetimibe) and the Merck Schering-Plough cholesterol joint venture's ENHANCE clinical trial. Forward-looking statements relate to expectations or forecasts of future events. Schering-Plough does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ materially from Schering-Plough's forward-looking statements, including economic factors, the government investigation process, the litigation process and the regulatory process, among other uncertainties. For further details about these and other factors that may impact the forward-looking statements, see Schering-Plough's Securities and Exchange Commission filings, including Part I, Item IA. "Risk Factors" in Schering-Plough's first quarter 2009 10-Q.

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**Prescribing information and patient product information for VYTORIN<sup>®</sup> and ZETIA<sup>®</sup> are attached.**