



## News Release

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### **Merck Announces HPS2-THRIVE Study of TREDAPTIVE™ (Extended Release Niacin/Laropiprant) Did Not Achieve Primary Endpoint**

WHITEHOUSE STATION, N.J., December 20, 2012 – Merck (NYSE:MRK), known outside the United States and Canada as MSD, today announced that the HPS2-THRIVE (Heart Protection Study 2-Treatment of HDL to Reduce the Incidence of Vascular Events) study of TREDAPTIVE™ (extended release niacin/laropiprant) did not meet its primary endpoint. Merck and the investigators are informing regulatory agencies of these results. The company is also preparing communications to health care providers in countries where the medicine is currently available, and will continue to work with regulators to provide updated information to health care providers. Based on the current understanding of these new data and until further analyses can be completed, Merck is recommending that providers not start new patients on TREDAPTIVE. Merck does not plan to seek regulatory approval for the medicine in the United States.

HPS2-THRIVE was independently conducted by the Clinical Trial Service Unit at Oxford University and funded by Merck. The study enrolled 25,673 patients considered to be at high risk for cardiovascular events. Of those enrolled, 14,741 were from Europe (the United Kingdom and Scandinavia) and 10,932 were from China. Patients in the study were followed for a median of 3.9 years. HPS2-THRIVE compared extended release niacin and laropiprant plus statin therapy versus statin therapy. It was not designed to assess directly the separate effects of either extended release niacin or laropiprant.

In the study, adding the combination of extended release niacin and laropiprant to statin therapy did not significantly further reduce the risk of the combination of coronary deaths, non-fatal heart attacks, strokes or revascularizations compared to statin therapy. In addition, there was a statistically significant increase in the incidence of some types of non-fatal serious adverse events in the group that received extended release niacin/laropiprant.

With the agreement of the independent research team at Oxford University, Merck is sharing results from the study with regulatory agencies in countries where the medicine is approved (under the brand names TREDAPTIVE or CORDAPTIVE) and in other countries as well. The investigators are conducting additional analyses, including regional analyses, to further understand the results. They anticipate reporting the detailed study results in the first quarter of 2013.

"While we are disappointed in these results, we thank the investigators who have conducted the study and the patients who have participated in it," said Peter S. Kim, Ph.D., president, Merck Research Laboratories. "We are committed to working closely with the independent research team at Oxford University and with regulatory agencies to understand the results and determine next steps."

#### **About TREDAPTIVE/CORDAPTIVE**

TREDAPTIVE/CORDAPTIVE has been approved in approximately 70 countries, including in Europe, and is sold in approximately 40 countries. TREDAPTIVE is also sold under the brand names PELZONT in Italy and TREVACLYN in Italy and Portugal. Sales through the first three quarters of 2012 were approximately \$13 million.

#### **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](http://www.merck.com) and connect with us on Twitter, Facebook and YouTube.

#### **Forward-Looking Statement**

This news release 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 2011 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](http://www.sec.gov)).

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