



NEWS RELEASE

## Jan7Merck Statement on FDA Advisory Committee Meeting for Suvorexant

5/22/2013

Merck (NYSE: MRK), known as MSD outside the United States and Canada, today provided the following statement after the conclusion of the Peripheral and Central Nervous System Drugs Advisory Committee meeting of the U.S. Food and Drug Administration (FDA) about suvorexant, Merck's investigational medicine to treat insomnia.

"We are excited about the potential of suvorexant as a new and different approach to treating insomnia, a serious condition that affects up to one-third of the adult population," said Darryle Schoepp, Ph.D., senior vice president and head of Neuroscience and Ophthalmology, Merck Research Laboratories. "Today's votes and discussion bring us one step closer to providing physicians with another option to help patients struggling with insomnia. We look forward to working with the FDA as the agency continues its review of our application."

If approved, suvorexant would be the first in a new class of medicines, called orexin receptor antagonists, for use in patients with insomnia, a condition characterized by difficulty falling asleep and/or staying asleep. Suvorexant's novel mechanism is distinct from current treatments. Merck researchers developed suvorexant to block the action of orexins, neurotransmitters in a specific part of the brain that help to keep a person awake. By temporarily blocking the actions of orexins, suvorexant helps to facilitate sleep.

The FDA will consider the Committee's recommendations as it completes its review of the New Drug Application (NDA) for suvorexant. The FDA is not bound by the Committee's guidance, but takes its advice into consideration when reviewing investigational medicines. Merck anticipates FDA action on suvorexant in mid-year. If approved by the FDA, suvorexant will become available after a schedule assessment and determination has been completed by

the U.S. Drug Enforcement Administration, which typically takes place after FDA approval.

## 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. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. 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](http://www.sec.gov)).

MerckMedia:Pam Eisele, 908-423-5042orTracy Ogden, 267-305-2301orInvestors:Carol Ferguson, 908-423-

4465orJustin Holko, 908-423-5088

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