



Published on *Merck Newsroom Home* (<https://www.mrknewsroom.com>) on 8/29/12 1:52 pm EDT

Merck and ARIAD Pharmaceuticals Provide Update on FDA Advisory Committee Vote on Investigational Medicine Ridaforolimus for the Treatment of Metastatic Soft-Tissue or Bone Sarcomas

Terms:

[Company Statements](#)

Published Date and Time:

3/20/12

WHITEHOUSE STATION, N.J. & CAMBRIDGE, Mass., March 20, 2012 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, and ARIAD Pharmaceuticals, Inc., (NASDAQ:ARIA), announced today that the U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 13 to 1 against the use of the investigational agent ridaforolimus as maintenance therapy for patients with metastatic soft-tissue sarcoma or bone sarcoma whose disease has not progressed after at least four cycles of chemotherapy.

The ODAC panel's recommendation will be considered by the FDA when making its decision regarding the New Drug Application (NDA) for ridaforolimus, an investigational oral mTOR inhibitor under development for the treatment of metastatic soft-tissue or bone sarcomas. The FDA is not bound by the Committee's guidance, but takes its advice into account.

"Merck remains confident in the potential of the investigational agent ridaforolimus for an indication where patients have limited options," said Eric Rubin, M.D., vice president, Clinical Research Oncology, Merck. "We remain committed to bringing forward this promising therapy for patients with metastatic sarcoma, and look forward to further discussions with the FDA regarding this application."

Sarcomas are a group of cancers of connective tissue of the body for which there are currently limited treatment options. Sarcomas can arise anywhere in the body and are divided into two main groups - bone tumors and soft-tissue sarcomas.

Ridaforolimus is an investigational small-molecule inhibitor of the protein mTOR, a protein that acts as a central regulator of protein synthesis, cell proliferation, cell cycle progression and cell survival, integrating signals from proteins, such as PI3K, AKT and PTEN, known to be important to malignancy.

Merck and ARIAD previously announced that the FDA has accepted for filing and review the New Drug Application (NDA) for ridaforolimus. As part of an exclusive license agreement with ARIAD, Merck is responsible for the development and worldwide commercialization of ridaforolimus in oncology. ARIAD intends to co-promote ridaforolimus in the United States. The trade name for ridaforolimus in the United States is TALTORVIC®.

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.

About ARIAD

ARIAD Pharmaceuticals, Inc. is an emerging global oncology company focused on the discovery, development and commercialization of medicines to transform the lives of cancer patients. ARIAD's approach to structure-based drug design has led to three internally discovered, molecularly targeted product candidates for drug-resistant and difficult-to-treat cancers, including certain forms of chronic myeloid leukemia, soft tissue and bone sarcomas and non-small cell lung cancer. For additional information, visit <http://www.ariad.com>.

Merck 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. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that all of the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; Merck's ability to accurately predict future market conditions;

dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to 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).

ARIAD Forward-Looking Statement

This statement contains "forward-looking statements" including, but not limited to, statements relating to clinical data for ridaforolimus in the treatment of metastatic soft-tissue and bone sarcomas. Forward-looking statements are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, results of clinical studies of the Company's product candidates, timing and acceptance of regulatory filings for drug approval, and other factors detailed in the Company's public filings with the U.S. Securities and Exchange Commission. The information contained in this press release is believed to be current as of the date of original issue. The Company does not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in the Company's expectations, except as required by law.

Language:

Select Language

Source URL: <https://www.mrknewsroom.com/news/company-statements/merck-and-ariad-pharmaceuticals-provide-update-fda-advisory-committee-vote-i>