



## News Release

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### **Merck and ARIAD Announce Presentation of Results of Phase III SUCCEED Trial at American Society of Clinical Oncology Annual Meeting**

#### **Oral Ridaforolimus, an Investigational Candidate, Achieved Primary Endpoint of Improved Progression-Free Survival in Patients with Metastatic Soft-tissue or Bone Sarcomas**

WHITEHOUSE STATION, N.J. and CAMBRIDGE, MA, June 6, 2011– Merck (NYSE:MRK), known outside the United States and Canada as MSD, and ARIAD Pharmaceuticals, Inc., (NASDAQ:ARIA), today announced the presentation of detailed results from the Phase III SUCCEED clinical trial. SUCCEED evaluated oral ridaforolimus, an investigational mTOR inhibitor, in patients with metastatic soft-tissue or bone sarcomas who previously had a favorable response to chemotherapy. In this patient population, ridaforolimus improved progression-free survival (PFS) compared to placebo, the primary endpoint of the study. The complete study results were presented by Sant P. Chawla, M.D., director of Medical Oncology, UCLA – Santa Monica Hospital and head, Sarcoma Oncology Center, Santa Monica, CA, during the 2011 American Society of Clinical Oncology (ASCO) annual meeting in Chicago.

Based on these results, Merck plans to submit a New Drug Application (NDA) for ridaforolimus to the U.S. Food and Drug Administration (FDA) and a marketing application in the European Union this year. "These data bring us one step closer to making ridaforolimus

available to patients with metastatic sarcoma who need it and reinforces our ongoing commitment to developing innovative therapies to treat cancer," said Eric Rubin, M.D., vice president of clinical oncology research at Merck.

### **Clinical Trial Results**

The SUCCEED (**S**arcoma **M**ulti-**C**enter **C**linical **E**valuation of the **E**fficacy of **R**idaforolimus) trial was a randomized (1:1), placebo-controlled, double-blind study of oral ridaforolimus administered at 40 mg/day (five of seven days per week) in patients with metastatic soft-tissue or bone sarcomas who previously had a favorable response to chemotherapy. Oral ridaforolimus was granted a Special Protocol Assessment (SPA) by the FDA for the SUCCEED trial.

Based on 552 progression-free survival (PFS) events in 711 patients, (ridaforolimus (N=347), placebo (N=364)) determined by an independent radiological review committee, the study achieved its primary endpoint of improvement in PFS, with a statistically significant ( $p=0.0001$ ) 28 percent reduction in the risk of progression or death observed in those treated with ridaforolimus compared to placebo (hazard ratio=0.72). Median PFS was 17.7 weeks for those treated with ridaforolimus compared to 14.6 weeks in the placebo group. Furthermore, based on the full analysis of PFS determined by investigator assessment, there was a statistically significant ( $p<0.0001$ ) 31 percent reduction by ridaforolimus in the risk of progression or death compared to placebo (hazard ratio=0.69). In the investigator assessment analysis, median PFS was 22.4 weeks for those treated with ridaforolimus compared to 14.7 weeks in the placebo group.

The independent radiological committee review analysis showed that the proportion of patients alive and free from disease progression in the ridaforolimus group compared to placebo was greater after three months (70 percent versus 54 percent), and six months (34 percent versus 23 percent).

Secondary endpoints were trends in overall survival (OS), best target lesion response, assessment of cancer-related symptoms, and safety and tolerability. Follow-up for OS is ongoing, and the current trend favors ridaforolimus: results at the most recent data cut-off (386 OS events) showed a median OS of 21.4 months for the oral ridaforolimus group compared to 19.2 months for the placebo arm (hazard ratio=0.88,  $p=0.2256$ ). For the best target lesion response, the oral ridaforolimus group showed an average target tumor lesion size reduction of 1.3 percent; whereas the placebo group showed an average target tumor lesion size increase of 10.3 percent ( $p<0.0001$ ). No conclusions could be drawn from the exploratory analysis of

cancer-related symptoms based on patient questionnaires about pain, cough and shortness of breath due to incomplete questionnaire data.

The most common severe (Grade  $\geq$  3) adverse events occurring at an incidence  $\geq$  7 percent in the ridaforolimus group compared to placebo were thrombocytopenia (10 percent versus 1 percent), stomatitis (9 percent versus  $<$  1 percent), anemia (7 percent versus 3 percent), and hyperglycemia (7 percent versus  $<$  1 percent). The most common side effects observed in the study were consistent with the known safety profile of ridaforolimus. The most common adverse events (all Grades) occurring at an incidence  $\geq$  30 percent in the ridaforolimus group compared to placebo were stomatitis (e.g. mouth sores) (61 percent versus 18 percent), infections (all sites included) (52 percent versus 26 percent), fatigue (36 percent versus 22 percent), thrombocytopenia (34 percent versus 4 percent), diarrhea (32 percent versus 18 percent) and cough (31 percent versus 16 percent). For adverse events that led to death, there were 6 deaths (1.8 percent) due to pulmonary disorders in the ridaforolimus treatment group and no deaths (0 percent) due to pulmonary disorders in the placebo group.

"Patients with metastatic soft-tissue and bone sarcomas have limited treatment options available to them. Data from the SUCCEED trial show that ridaforolimus maintained the benefit of prior conventional chemotherapy," said Dr. Chawla. "The study met the primary endpoint of progression-free survival, showing a clinically meaningful and statistically significant improvement in PFS in those patients treated with oral ridaforolimus."

"These updated data illustrate how challenging metastatic sarcomas can be, even in patients who have responded favorably to chemotherapy," said Harvey J. Berger, M.D., chairman and chief executive officer of ARIAD. "We are pleased with the results of the SUCCEED trial and look forward to Merck filing for marketing approval of ridaforolimus."

As part of an exclusive license agreement with ARIAD, Merck is responsible for the development and worldwide commercialization of ridaforolimus in oncology.

### **ARIAD Investor Call Today, June 6, at 5:45-6:45 p.m. CT**

ARIAD will hold an investor briefing today, Monday, June 6, from 5:45-6:45 p.m. CT at the Renaissance Blackstone Hotel to discuss the comprehensive data from the Phase III SUCCEED trial. Sant Chawla, M.D., director of Medical Oncology at the University of California Los Angeles-Santa Monica Hospital, will join members of ARIAD's management team for the briefing. This meeting will be webcast live and can be accessed by visiting the investor relations section of ARIAD's website at: <http://investor.ariad.com> or by dialing 800-265-0241 (domestic) or 617-847-8704 (international) five minutes prior to the start time and providing the pass code 91808133.

A replay of this investor event will be available on the ARIAD website approximately three hours after the presentation and will be archived for three weeks.

### **About Sarcomas**

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.

### **About Ridaforolimus**

Ridaforolimus is an investigational targeted and potent 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.

### **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).

### **About ARIAD**

ARIAD's vision is to transform the lives of cancer patients with breakthrough medicines. The Company's mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest and most urgent unmet medical need - aggressive cancers where current therapies are inadequate. ARIAD's product candidate, ridaforolimus, is an investigational mTOR inhibitor being developed by Merck that has successfully completed a Phase 3 clinical trial in patients with soft-tissue and bone sarcomas and is being studied in multiple cancer indications. ARIAD's second internally discovered product candidate, ponatinib, is an investigational pan-BCR-ABL inhibitor in a pivotal Phase 2 clinical trial in patients with chronic myeloid leukemia and Ph+ acute lymphoblastic leukemia. For additional information, please visit <http://www.ariad.com>.

### **Merck 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. 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 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; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck’s ability to accurately predict future market conditions; dependence on the effectiveness of Merck’s patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally 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 2010 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)).

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

This press release 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.

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