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News Release

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ARIAD REPORTS TUMOR REGRESSION WITH AP23573 AS A SINGLE AGENT IN PATIENTS WITH RELAPSED AND/OR REFRACTORY CANCER

Updated Phase 1 Clinical Results on Novel mTOR Inhibitor Presented at International Cancer Symposium

Cambridge, MA, September 30, 2004 – ARIAD Pharmaceuticals, Inc. (Nasdaq: ARIA) today announced, for the first time, updated results of two Phase 1 clinical trials of its novel mTOR inhibitor, AP23573 as a single agent, showing documented tumor regression in patients with advanced cancers – most of whom had progressive disease upon entering the trial and virtually all of whom had failed alternative treatments. These clinical results are being presented today at the 2004 EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Geneva, Switzerland.

Combined Trial Results: Anti-tumor Responses

Of 49 evaluable patients in the two trials, tumor regression was demonstrated in 9 patients (4 "partial responses" by RECIST with at least 30% reduction in tumor size and 5 "minor responses" with 15% to 29% reduction). In an additional 15 patients, disease stabilization was achieved. Overall, 49% (24 of 49) of the patients in the two trials had documented anti-tumor responses (including partial and minor responses and stable disease), with a median response of 5 months in those demonstrating anti-tumor responses, extending to greater than 18 months – the longest treatment to date.

Anti-tumor responses were demonstrated in 9 different refractory and/or relapsed cancers, including all evaluable patients with sarcoma (5 of 5), kidney cancer (7 of 7) and lymphoma (1 of 1), as well as 2 of 3 patients with non-small cell lung (NSCL) cancer.

"We are extremely encouraged by the number of patients with relapsed and/or refractory cancer who demonstrated tumor regression with AP23573 in Phase 1 clinical trials, as well as the breadth of tumors that are responding to our novel mTOR inhibitor," said Harvey J. Berger, M.D., chairman and chief executive officer of ARIAD. "As a clinician, I was particularly struck by the results in one patient with a Ewing's sarcoma who had received nine prior anticancer regimens. After four cycles of AP23573, CT scans showed a 62% reduction in the size of the mass; this patient continues on study. Phase 2 studies of AP23573 are ongoing in patients with hematologic cancers and solid tumors."

Daily Dosing Trial Results

In the 27 evaluable patients in the daily dosing trial – the dosing regimen being used in current Phase 2 clinical trials – AP23573 produced tumor regression in 7 patients:

- Partial response – Sarcoma, lymphoma, and NSCL cancer (1 each)
- Minor response – Sarcoma, NSCL, kidney, and thyroid cancers (1 each).

An additional 9 patients in this trial had stabilization of their disease (overall 59% with anti-tumor response).

Weekly Dosing Trial Results

In the 22 evaluable patients in the weekly dosing trial, AP23573 also produced tumor regression in 2 patients, both with particularly difficult-to-treat cancers, even when the drug was administered only once each week:

- Partial response – Bladder cancer (1) (unconfirmed, repeat scans pending)
- Minor response – Mesothelioma, a form of chest-cavity cancer (1).

An additional 6 patients in this trial had stabilization of their disease (overall 36% with anti-tumor response).

Additional Combined Trial Results

The daily dosing trial is ongoing at the Institute for Drug Development, Cancer Therapy and Research Center, San Antonio (M. Mita, M.D. and A. Tolcher, M.D.), and the weekly dosing trial is ongoing at the University of Chicago Cancer Center (A. Desai, M.D. and M. Ratain, M.D.).

AP23573 has been well tolerated by patients in both trials, with generally mild or moderate, readily reversible adverse events. The dose-limiting toxicity was severe oral mucositis, an inflammatory irritation of the mucous membranes of the mouth and a common finding in cancer patients on various types of treatments.

Pharmacodynamic assays on patient samples demonstrated a good correlation of blood levels of AP23573 with inhibition of AP23573's molecular target, the protein mTOR. Greater than 90% inhibition was observed within 1 hour after dosing in all patients in both trials. With daily dosing of AP23573, there was sustained inhibition of mTOR activity for up to 10 days in the majority of patients studied.

The pharmacokinetic (blood-clearance) profile of AP23573 was found to be highly predictable and reproducible, with a median half-life of 49 hours for all patients with complete data in the two trials. In contrast to other mTOR inhibitors in clinical trials, AP23573 was stable *in vivo* and is not a pro-drug.

About AP23573

The small-molecule drug, AP23573, starves cancer cells and shrinks tumors by inhibiting the critical cell-signaling protein, mTOR, which regulates the response of tumor cells to nutrients and growth factors, and controls tumor blood supply and angiogenesis through effects on Vascular Endothelial Growth Factor (VEGF).

About the Company

ARIAD is engaged in the discovery and development of breakthrough medicines to treat cancer by regulating cell signaling with small molecules. The Company is developing a comprehensive approach to patients with cancer that addresses the greatest medical need – aggressive and advanced-stage cancers for which current treatments are inadequate. ARIAD also has an exclusive license to pioneering technology and patents related to certain NF-κB treatment

methods, and the discovery and development of drugs to regulate NF-κB cell-signaling activity, which may be useful in treating certain diseases. Additional information about ARIAD can be found on the web at http://www.ariad.com.

Some of the matters discussed herein are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are identified by the use of words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. Such statements are based on management's current 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 forward-looking statements. These risks include, but are not limited to, risks and uncertainties regarding the Company's ability to accurately estimate the actual research and development expenses and other costs associated with the preclinical and clinical development of our product candidates, the adequacy of our capital resources and the availability of additional funding, risks and uncertainties regarding the Company's ability to successfully conduct preclinical and clinical studies of its product candidates, risks and uncertainties that clinical trial results, such as those noted in this press release, at any phase of development may be adverse or may not be predictive of future result or lead to regulatory approval of any of the Company's product candidates, and risks and uncertainties relating to regulatory oversight, intellectual property claims, the timing, scope, cost and outcome of legal proceedings, future capital needs, key employees, dependence on the Company's collaborators and manufacturers, markets, economic conditions, products, services, prices, reimbursement rates, competition and other risks detailed in the Company's public filings with the Securities and Exchange Commission, including ARIAD's Annual Report on Form 10-K for the fiscal year ended December 31, 2003. The information contained in this document 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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