



ArQule Provides Update on ARQ 197 Presentations at ASCO 2010

WOBURN, Mass., May 21, 2010 (BUSINESS WIRE) -- ArQule, Inc. (Nasdaq: ARQL) today announced that the following presentations of clinical data for ARQ 197, a selective inhibitor of the c-Met receptor tyrosine kinase, will take place at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held June 4-8, 2010 in Chicago, Illinois.

- Clinical Science Symposium - Oral presentation #LBA7502: Results from ARQ 197-209: A global randomized placebo-controlled phase II clinical trial of erlotinib plus ARQ 197 versus erlotinib plus placebo in previously treated EGFR inhibitor-naïve patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). The symposium will take place on Saturday, June 5, 2010 from 8:00 AM - 9:30 AM, with the presentation time scheduled to begin at 9:00 AM. Note: this is a late-breaking abstract submission, the embargo for which will be lifted on June 5, 2010.
- Poster Discussion Session - Poster #3024: A phase I dose-escalation trial evaluating ARQ 197 administered in combination with sorafenib in adult patients (pts) with advanced solid tumors; poster to be presented on Sunday, June 6, 2010 from 2:00 PM - 6:00 PM (poster discussion: 5:00 P.M. - 6:00 P.M)
- General Poster Session - Poster #4137: Final results from ARQ 197-114: A phase Ib safety trial evaluating ARQ 197 in cirrhotic patients (pts) with hepatocellular carcinoma (HCC); to be presented on Sunday, June 6, 2010 from 2:00 PM - 6:00 PM.
- Trials in Progress Poster Session - Poster #TPS215: ARQ 197-215: A randomized, placebo-controlled phase II clinical trial evaluating the c-Met inhibitor, ARQ 197, in patients (pts) with hepatocellular carcinoma (HCC); to be presented on Monday, June 7, 2010, 8:00 AM - 12:00 PM.

About ArQule

ArQule is a biotechnology company engaged in the research and development of next-generation, small-molecule cancer therapeutics. The Company's targeted, broad-spectrum products and research programs are focused on key biological processes that are central to human cancers. ArQule's lead product, in Phase 2 clinical development, is ARQ 197, an inhibitor of the c-Met receptor tyrosine kinase. The Company is also conducting Phase 1 clinical testing with ARQ 621, designed to inhibit the Eg5 kinesin motor protein. The Company's pre-clinical pipeline includes a compound designed to inhibit the BRAF kinase. ArQule's current discovery efforts, which are based on the ArQule Kinase Inhibitor Platform (AKIP™), are focused on the identification of novel kinase inhibitors that are potent, selective and do not compete with ATP (adenosine triphosphate) for binding to the kinase. These include a series of small molecule inhibitors of fibroblast growth factor receptor (FGFR).

This press release refers to public presentations that contain statements regarding the Company's clinical trials with ARQ 197. These statements are based on the Company's current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. Positive information about pre-clinical and early stage clinical trial results does not ensure that later stage or larger scale clinical trials will be successful. For example, ARQ 197 may not demonstrate promising therapeutic effect; in addition, it may not demonstrate an appropriate safety profile in current or later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing these compounds that could lead the Company or its partners to discontinue development. Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from analysis of data or from additional data or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with the Company's view of the data or require additional data or information or additional studies. In addition, the planned timing of initiation and completion of clinical trials for ARQ 197 are subject to the ability of the Company or Daiichi Sankyo, Inc., its partner, and Kyowa Hakko Kirin, a licensee of ARQ 197, to enroll patients, enter into agreements with clinical trial sites and investigators, and overcome other technical hurdles and issues related to the conduct of the trials that may not be resolved. Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Positive pre-clinical data may not be supported in later stages of development. Furthermore, ArQule may not have the financial or human resources to successfully pursue drug discovery in the future. Moreover, Daiichi Sankyo has certain rights to unilaterally terminate the ARQ 197 license, co-development and co-commercialization agreement. If it were to do so, the Company might not be able to complete development and commercialization of ARQ 197 on its own. For more detailed information on the risks and uncertainties associated with the Company's drug development and other activities, see the Company's periodic reports filed with the Securities and Exchange Commission. The Company does not undertake any obligation to publicly update any forward-looking statements.

SOURCE: ArQule, Inc.

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