For Immediate Release

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DAIICHI SANKYO AND ARQULE ANNOUNCE TOP-LINE RESULTS OF PHASE 2 TRIAL WITH TIVANTINIB IN COLORECTAL CANCER

Tokyo, Japan (January 15, 2013)-Attached is the co-press release with ArQule, Inc., which was issued on January 11, 2013 (US time).

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Tivantinib in combination with irinotecan and cetuximab shows a trend of prolonged progression free survival and improved objective response rate in signal generation trial

Tokyo, Japan and Woburn, MA – January 11, 2013 – Daiichi Sankyo Company, Limited (TSE 4568) and ArQule, Inc. (Nasdaq: ARQL) today announced the top-line results of a randomized Phase 2 signal generation trial of tivantinib (ARQ 197) used in combination with irinotecan and cetuximab in patients with refractory or relapsed colorectal cancer (CRC). Although the trial did not meet its primary endpoint of Progression-Free Survival (PFS), the analysis of the patients enrolled (n=122) showed that median PFS was 8.3 months in the experimental arm (patients treated with irinotecan and cetuximab plus tivantinib), compared with 7.3 months in the control arm (patients treated with irinotecan and cetuximab plus placebo) (hazard ratio = 0.85, 95% CI: 0.55, 1.33). Objective Response Rate (ORR), a secondary endpoint, was 45 percent in the experimental arm versus 33 percent in the control arm but was not statistically significant. The PFS results obtained in both the control arm and the experimental arm were longer than expected compared to previously published historical norms.

Additional data and analyses from this trial are planned for presentation at a future medical meeting and will include mature OS data as well as analyses of patient sub-groups, biomarker status and regional variability, including pre- and post study treatments.

“We are encouraged by these findings that expand the body of data for tivantinib in CRC and offer the potential for further exploration,” said Reinhard von Roemeling, M.S., Vice President, Clinical Development - Oncology, Daiichi Sankyo. “We plan to continue discussions with key opinion leaders in the field of CRC to determine how best to proceed with further clinical development of tivantinib in this tumor type.”

Adverse events were reported at similar rates in the experimental and control arms, except for increased neutropenia observed in the experimental arm, with no discontinuations of treatment for this reason. No treatment-emergent adverse events leading to death were assessed as related to study treatment. Tivantinib was generally well tolerated in combination with the doses of cetuximab and irinotecan studied in this trial.

About the Phase 2 Trial

The 122 patients enrolled in this trial (US n=67; Russia n=39; Western Europe n=16) had unresectable CRC, progressed following first-line treatment and had tumors expressing the wild-type form of the KRAS gene. The primary objective of the trial was to assess the contribution of tivantinib to the irinotecan and cetuximab treatment regimen. The primary endpoint of the study was PFS, and secondary objectives included OS and ORR. Patients were randomized to receive tivantinib, 360 milligrams twice daily, plus irinotecan and cetuximab, or placebo plus irinotecan and cetuximab. The trial was conducted by Daiichi Sankyo, the co-developer with ArQule of tivantinib in all regions outside of certain territories in Asia.

About Colorectal Cancer (CRC)

Colorectal cancer is the second leading cause of cancer-related deaths in the U.S. and is the third most common cancer in men and women. According to the National Cancer Institute, it is estimated that more than 140,000 new cases of colorectal cancer will be diagnosed in 2012, and an estimated 51,700 deaths from the disease will occur this year. The estimated incidence rate was 46 per 100,000 people during the period 2005-2009.

About MET and Tivantinib (ARQ 197)

Tivantinib is an orally administered, selective inhibitor of MET, a receptor tyrosine kinase, which is currently in Phase 2 clinical trials. In certain healthy adult cells, MET is present in low to normal levels to support natural cellular function, but in some cancer cells, MET is inappropriately and continuously activated. When abnormally activated, Met plays multiple roles in aspects of human cancer, including cancer cell growth, survival, angiogenesis, invasion and metastasis.

Pre-clinical data have demonstrated that tivantinib inhibits MET activation in a range of human tumor cell lines and shows anti-tumor activity against several human tumor xenografts. In clinical trials to date, treatment with tivantinib has been generally well tolerated and has shown clinical activity in the tumors studied. Tivantinib has not yet been approved for any indication in any country.

About ArQule, Inc. and Daiichi Sankyo, Co., Ltd.

On December 19, 2008, ArQule and Daiichi Sankyo, Co., Ltd. signed a license, co-development and co-commercialization agreement to co-develop tivantinib in the U.S.,

Europe, South America and the rest of the world, excluding Japan, China (including Hong Kong), South Korea and Taiwan, where Kyowa Hakko Kirin Co., Ltd. has exclusive rights for development and commercialization.

About Daiichi Sankyo

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

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 tivantinib (ARQ 197), an oral, selective inhibitor of the MET receptor tyrosine kinase. The Company's pipeline consists of ARQ 621, designed to inhibit the Eg5 kinesin motor protein, and ARQ 736, designed to inhibit the RAF kinases. 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.

This press release contains forward-looking statements regarding the clinical trials with tivantinib in combination with irinotecan and cetuximab in colorectal cancer conducted by the Company and Daiichi Sankyo Co., Ltd. as well as the Company's agreement with Daiichi Sankyo. 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, tivantinib alone or in a combination therapy may not demonstrate promising therapeutic effects in such trials; in addition, such therapies may not demonstrate an appropriate safety profiles in later stage or larger scale clinical trials, including among patients with underlying cirrhosis and compromised liver function, 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 or to justify further development. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing tivantinib or in obtaining irinotecan and cetuximab that could lead the Company or its partners to discontinue development. Even if later stage clinical trials are successful, unexpected concerns may arise from analysis of data or from additional data. Obstacles may arise or issues may be identified in connection with review of clinical data

with regulatory authorities, and 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 tivantinib alone or in a combination therapy is subject to the ability of the Company or Daiichi Sankyo, its partner, 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 for which each of them is responsible 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 tivantinib 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 tivantinib 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.