

For Immediate Release

Company name: DAIICHI SANKYO COMPANY, LIMITED

Representative: Joji Nakayama, President and CEO

(Code no.: 4568, First Section of Tokyo, Osaka and Nagoya Stock Exchanges)

Please address inquiries to Toshiaki Sai, Corporate Officer,

Vice President, Corporate Communications Department

Telephone: +81-3-6225-1126 (Public Relations)

+81-3-6225-1125 (Investor Relations)

<http://www.daiichisankyo.com/>

**Daiichi Sankyo and ArQule Enroll First Non-Small Cell Lung Cancer Patient
into Global Phase III Trial For ARQ 197**

Attached is the co-press release with ArQule, Inc., which was issued on January 12, 2011.(US time)



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**Daiichi Sankyo and ArQule Enroll First Non-Small Cell Lung Cancer Patient
into Global Phase III Trial For ARQ 197**

Tokyo, Japan and Woburn, MA – January 12, 2011 – Daiichi Sankyo Company, Limited (TSE 4568) and ArQule, Inc. (Nasdaq: ARQL) today announced that the first patient has been enrolled in the Phase III trial of ARQ 197, an investigational selective inhibitor of the c-Met receptor tyrosine kinase, in combination with erlotinib, for patients diagnosed with non-squamous, non-small cell lung cancer (NSCLC), who have received one or two prior systemic anti-cancer therapies.

The Phase III trial is a randomized, double-blinded, controlled study of previously treated patients with locally advanced or metastatic, non-squamous NSCLC who will receive ARQ 197 plus erlotinib or placebo plus erlotinib.

The primary objective is to evaluate the overall survival (OS) in the intent-to-treat (ITT) population. Secondary endpoints include OS in the subpopulation of patients with epidermal growth factor receptor (EGFR) wild type, progression-free survival (PFS) in the ITT population, and further assessment of the safety of ARQ 197 in combination with erlotinib.

According to the International Agency for Research on Cancer, more than 1.6 million new cases of lung cancer were diagnosed in 2008 globally,¹ and NSCLC accounted for 80 percent of those cases.² According to the American Cancer Society more than 220,000 cases of lung cancer will have been diagnosed in 2010 in the U.S.³ Of patients diagnosed with lung cancer in Europe, almost 90 percent die of the disease.⁴

“With lung cancer accounting for more deaths than colon, breast and prostate cancers combined,⁵ we are very pleased to begin this Phase III trial to advance the knowledge about the role ARQ 197 might have in the treatment of patients with non-small cell lung cancer in combination with erlotinib,” said Dr. Kazunori Hirokawa, global head of R&D Unit, Daiichi Sankyo. “It is our hope and expectation that this late-stage study will confirm the results we observed in patients with non-squamous cell histology in Phase II, which showed promise toward extending overall survival and progression-free survival in this group when ARQ 197 was combined with erlotinib.”

“The start of this Phase III trial marks a key milestone in the development of ARQ 197 and our partnership with Daiichi Sankyo,” said Paolo Pucci, chief executive officer of ArQule. “Lung cancer is a devastating disease, and our hope is that ARQ 197 will prove to be an effective treatment option that will help patients diagnosed with this disease.”

In October 2010, agreement was reached with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the Phase III trial comparing ARQ 197 plus erlotinib against erlotinib plus placebo. The Phase III study of ARQ 197 plus erlotinib

¹ International Agency for Cancer Research, URL: <http://globocan.iarc.fr/factsheets/cancers/lung.asp>. Last accessed November 10, 2010.

² American Cancer Society. Lung Cancer. URL: <http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/OverviewGuide/lung-cancer-non-small-cell-overview-non-small-cell-lung-cancer>. Last accessed November 10, 2010.

³ American Cancer Society. Lung Cancer. URL: <http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/OverviewGuide/lung-cancer-non-small-cell-overview-key-statistics>. Last accessed November 9, 2010.

⁴ (GLOBOCAN 2008) International Agency for Research on Cancer: <http://globocan.iarc.fr>

⁵ American Cancer Society. Lung Cancer. URL: <http://www.cancer.org/Cancer/LungCancer-Non-SmallCell/DetailedGuide/non-small-cell-lung-cancer-key-statistics>. Last accessed November 9, 2010.

will enroll 988 patients in 150 sites in the U.S., Canada, Eastern and Western Europe, Australia and Latin America. Additional details are available on www.clinicaltrials.gov.

About ARQ 197 and c-Met

ARQ 197 is an orally available, selective inhibitor of c-Met, a receptor tyrosine kinase that is currently in Phase II and Phase III clinical trials and is not yet approved for use. In healthy adult cells, c-Met is present in normal levels to support natural cellular function, but in cancer cells, c-Met is inappropriately and continuously activated for unknown reasons. When abnormally activated, c-Met plays multiple roles in aspects of human cancer, including cancer cell growth, survival, angiogenesis, invasion and metastasis.

Pre-clinical data have demonstrated that ARQ 197 inhibits c-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 ARQ 197 has been well-tolerated and has resulted in tumor responses and prolonged stable disease across a broad range of tumors.

In December 2008, ArQule and Daiichi Sankyo signed a license, co-development and co-commercialization agreement to co-develop ARQ 197 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.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.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 II and Phase III clinical development, is ARQ 197, an inhibitor of the c-Met receptor tyrosine kinase. The Company has also initiated Phase 1 clinical testing with ARQ 621, designed to inhibit the Eg5 kinesin motor protein, and with 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 progress of the Companies' Phase 2 and Phase 3 clinical trials with ARQ 197. These statements are based on the Companies' current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. Positive information about early stage clinical trial results is not necessarily indicative of clinical efficacy and does not ensure that later stage or larger scale clinical trials will be successful. 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 Companies or their collaborators 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 Companies' views of the data or require additional data, information or studies. For example, ARQ 197 may not demonstrate promising therapeutic effect; in addition, this compound may not demonstrate an appropriate safety profile in further

pre-clinical testing and in current, later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. In addition, the planned timing of initiation and completion of clinical trials for ARQ 197 is subject to the ability of the Companies to enroll patients, enter into agreements with clinical trial sites and investigators, and other technical hurdles and issues 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. Furthermore, ArQule may not have the financial or human resources to pursue drug discovery successfully in the future. 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.

For more information, please contact:

William B. Boni
ArQule, Inc.
(781) 994-0300

Toshiaki Sai
Daiichi Sankyo, Co.,
Ltd. (Japan)
+81-3-6225-1126

Kimberly Wix
Daiichi Sankyo, Inc.
(US)
(973) 944-2338

Tetsuya Ohira
Daiichi Sankyo Europe
+49 (0) 89-7808-694

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