Virginia Cancer Specialists First in the World to Enroll Patient in Cutting-Edge Lung Cancer Clinical Trial

Practice leads the way in bringing promising potential new therapy to patients with ALK-positive non-small cell lung cancer

Fairfax, Va. (July 14, 2016) — Virginia Cancer Specialists (VCS), Virginia’s premier cancer care center with more than 40 years of providing service to patients battling cancer and blood diseases, is the first in the world to enroll a patient in a new advanced lung cancer clinical trial that may hold promise for patients with ALK-positive locally advanced or metastatic non-small cell lung cancer (ALK+ NSCLC). The randomized Phase III clinical trial focuses on brigatinib, an investigational anaplastic lymphoma kinase (ALK) inhibitor from ARIAD Pharmaceuticals, Inc. The trial is designed to assess the efficacy of the drug candidate in a head-to-head comparison with the current recommended therapy, crizotinib, evaluating progression free survival.

Virginia Cancer Specialists conducts clinical trials through US Oncology Research, one of the largest community-based cancer research programs in the country. US Oncology Research has played a role in approximately 60 FDA approved cancer therapies, nearly one-third of all approved cancer therapies to date. Other practices affiliated with US Oncology Research are also participating in the trial. The trial is expected to be conducted at approximately 150 investigational sites in North America, Europe and the Asia Pacific region.

“We are excited to be the very first cancer practice in the world to enroll a patient in this important Phase III trial that may eventually lead to improved outcomes for patients battling certain forms of non-small cell lung cancer,” said Alex Spira M.D., medical oncologist and director of the VCS Research Institute. “As the leader in clinical research in Northern Virginia, we are committed to advancing the fight against cancer by bringing cutting-edge clinical trials, like the brigatinib study, to our region, providing patients access to novel investigational therapies in a convenient community setting. Rather than traveling elsewhere for these advanced investigational treatments, patients can receive care in a comfortable, familiar environment close to home where they have the ongoing support of family and friends, helping them achieve the best possible outcome.”

The Phase III clinical trial of brigatinib was launched in April, and the VCS Research Institute immediately began screening patients for eligibility, eventually identifying the patient who would become the very first in the world to enroll in this advanced clinical study.

“Our pivotal trial of brigatinib explored its safety and efficacy for patients following crizotinib. Virginia Cancer Specialists and other clinical trial sites are also examining brigatinib’s potential as a new therapy for patients with ALK+ NSCLC who have not yet received an ALK inhibitor. Innovative therapies are needed for these patients to improve response rates and delay progression that can occur through the emergence of secondary resistance mutations in ALK, and progression in the central nervous system.” said Tim Clackson, Ph.D., president of research and development and chief scientific officer of ARIAD. “We believe that the encouraging results shown in our preclinical and ongoing Phase I and II studies suggest brigatinib has the potential to improve outcomes for ALK+ treatment-naïve patients by suppressing ALK+ disease.”

Brigatinib has received breakthrough designation from the US Food and Drug Administration (FDA), and ARIAD recently commenced submission of a New Drug Application for initial approval in patients who have experienced crizotinib failure. In June, the FDA cleared brigatinib for an Expanded Access Program (EAP), also called “compassionate use,” a special program allowing manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in another clinical trial. The EAP for brigatinib will provide the drug candidate to patients who have experienced failure of at least one prior ALK inhibitor, who cannot meet eligibility criteria for other trials.
due to a variety of reasons such as poor performance status, lack of geographic proximity, or because other medical interventions are not considered appropriate or acceptable.

"Lung cancer is the leading cause of cancer-related deaths in the United States and is extremely difficult to treat because there are so many different mutations," explained Raymond Wadlow, M.D., medical oncologist and co-director of the VCS Research Institute. "The brigatinib Phase III clinical trial may eventually provide a potential new therapy for patients with ALK+ NSCLC, an area where more innovative therapies are desperately needed to improve response rates. Meanwhile, the Expanded Access Program will give another option to patients who have experienced failure of another TKI, offering the potential opportunity for improved outcomes to patients who are battling this complex disease."

Patients 18 years or older with locally advanced and/or metastatic ALK+ NSCLC who are interested in participating in the clinical trial or Expanded Access Program for brigatinib can contact the VCS Research Institute at (703) 208-3192 to learn more about the criteria for participation.

The VCS Research Institute is a valuable resource for the regional medical community and is well-respected among referring physicians, patients and payers who recognize the practice’s long-standing commitment to provide the very latest treatment options to patients. Drs. Spira and Wadlow oversee a team of highly-skilled oncology research professionals who work with VCS oncologists to provide clinical trials at six convenient treatment sites throughout the area.

"We are extremely proud to conduct and enroll the very first patient in the world in the brigatinib clinical trial, as it demonstrates our leadership role in bringing exciting new therapies to cancer patients, not only in our local community, but across the global cancer community as well," noted Karin Choquette, MSN, RN, CCRC, clinical research manager at VCS. "We are committed to leading the way in the fight against cancer while providing our patients access to the world's most advanced cancer treatments and cutting-edge clinical trials."

About Virginia Cancer Specialists
For more than 40 years, Virginia Cancer Specialists has contributed to the campaign against cancer and diseases of the blood. VCS has nine locations throughout Northern Virginia staffed by more than 30 highly-skilled physicians, each delivering exceptional care. The practice has built a world-class treatment team of cancer specialists, as well as acquiring the very latest treatment technology to help achieve the best outcomes for patients. VCS unites medical, radiation, and orthopedic oncologists, hematologists, oncology nurse navigators, oncology infusion nurses, radiation therapists, genetic counselors, oncology pharmacists and laboratory technicians, all working together as a team to design the optimal multidisciplinary treatment program, efficiently sharing knowledge, executing the treatment plan, and providing a patient-centered, consumer-friendly approach to cancer care. Patients receive the full spectrum of high-quality care necessary to treat their disease from a care team united in their effort to provide each patient with the specific personalized care they need to battle cancer.

Virginia Cancer Specialists has a well-established, comprehensive clinical research program and is one of the only fully staffed cancer centers committed to research in Northern Virginia. The practice has access to hundreds of innovative clinical trials through its affiliation with The US Oncology Network, one of the nation’s largest associations of community-based oncologists and a leader in the advancement of cancer research and treatment. The US Oncology Network conducts clinical research through US Oncology Research, which has played a role in approximately 60 FDA-approved cancer therapies. US Oncology Research manages about 300 active trials at any given time, and VCS participates in many of them, testing new leading-edge drugs or various combinations of treatments for cancer and blood disorders. To learn more about Virginia Cancer Specialists, please visit www.VirginiaCancerSpecialists.com.

Forward-Looking Statements
This press release contains forward-looking statements by or about ARIAD Pharmaceuticals, Inc., each of which is qualified in its entirety by this cautionary statement. Any statements contained herein which do not describe historical facts, including, but not limited to statements regarding design, enrollment and anticipated timing for the Phase III clinical trial of brigatinib; the therapeutic potential for
brigatinib; and the statements made by Dr. Clackson, are forward-looking statements that are based on ARIAD 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 factors, risks and uncertainties include, but are not limited to, ARIAD’s ability to successfully commercialize and generate profits from sales of Iclusig and its product candidates, if approved; competition from alternative therapies; ARIAD’s ability to meet anticipated clinical trial commencement, enrollment and completion dates and regulatory filing dates for its products and product candidates and to move new development candidates into the clinic; ARIAD’s ability to execute on its key corporate initiatives; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory and pricing and reimbursement approvals to market its products; ARIAD’s reliance on the performance of third-party manufacturers and specialty pharmacies for the supply and distribution of its products and product candidates; the occurrence of adverse safety events with ARIAD’s products and product candidates; the costs associated with ARIAD’s research, development, manufacturing, commercialization and other activities; the conduct, timing and results of preclinical and clinical studies of ARIAD’s products and product candidates, including that preclinical data and early-stage clinical data may not be replicated in later-stage clinical studies; the adequacy of ARIAD’s capital resources and the availability of additional funding; the ability to satisfy ARIAD’s contractual obligations, including under its leases, convertible debt and royalty financing agreements; patent protection and third-party intellectual property claims; litigation; ARIAD’s operations in foreign countries; risks related to ARIAD’s key employees, markets, economic conditions, health care reform, prices and reimbursement rates; and other risk factors detailed in ARIAD’s public filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release and ARIAD undertakes no obligation to update or revise any of these statements to reflect events or circumstances occurring after this press release. ARIAD cautions investors not to place considerable reliance on the forward-looking statements contained in this press release.

Media Contact
Claire Crye
US Oncology Research
281-825-9927
Claire.Crye@usoncology.com

###