Astellas and Ambit Initiate Phase 2b Dose Finding Study of Quizartinib as Monotherapy in Relapsed or Refractory Acute Myeloid Leukemia

Tokyo, Japan and San Diego, Calif., - June 4, 2012 – Astellas Pharma Inc. (Tokyo: 4503, Astellas) and Ambit Biosciences Corporation today announced the initiation of a Phase 2b open-label clinical trial of quizartinib as monotherapy in patients with relapsed and refractory acute myeloid leukemia (AML) with FLT3-ITD mutations.

The trial will enroll 64 adult patients (the estimated enroll of the protocol) in the United States and Europe to evaluate two oral doses of quizartinib in 28-day cycles. The co-primary endpoints of the study are (i) the composite complete response (CRc) rate, defined as the sum of complete remission (CR), complete remission with incomplete platelet recovery (CRp) and complete remission with incomplete hematologic recovery (CRi), and (ii) the Grade 2 or higher QT interval prolongation at each dose level. The trial was designed based on the results from an interim analysis of the ACE trial (another monotherapy Phase 2 trial conducted by Ambit), which were presented last year at the American Society of Hematology Meeting. The 333 patients included in the ACE trial were either at least 60 years old and relapsed or refractory to first-line chemotherapy (Cohort 1), or at least 18 years old and relapsed or refractory to second-line chemotherapy or hematopoietic stem cell transplantation (HSCT) (Cohort 2). Final results of the ACE trial will be presented later this year at a medical conference.

“AML is amongst the most challenging hematological malignancies to treat, and very few treatment advances have been made in several decades,” said Jorge Cortes, M.D., primary investigator for the ACE study, internist and professor, deputy chair of the department of leukemia in the division of cancer medicine at The University of Texas M.D. Anderson Cancer Center. “A significant portion of AML patients have activating FLT3 mutations, and these patients have a particularly poor prognosis and often relapse or are refractory to current treatment options. We look forward to exploring the full potential of quizartinib as a new option for patients.”

Added Athena Countouriotis, M.D., chief medical officer of Ambit, “We are very encouraged by the Cohort 2 response rate and overall survival data from the ACE trial and look forward to presenting the results at a medical conference later this year. The Phase 2b dose finding study will evaluate lower doses of quizartinib to allow us to continue to maximize the level of efficacy seen with an improved tolerability profile.”

About Quizartinib

Quizartinib, formerly known as AC220, is being developed in collaboration between Ambit Biosciences Corporation and Astellas Pharma Inc. and is a novel, potent, highly selective, orally bioavailable FMS-like tyrosine kinase-3 (FLT3) inhibitor. Quizartinib is currently under evaluation in Phase 2 and Phase 2b clinical trials as monotherapy treatment for adult patients with relapsed or refractory AML that have aninternal tandem duplication (ITD) mutation in the FLT3 gene.

About Ambit Biosciences

Ambit Biosciences is a privately held biopharmaceutical company engaged in the development of a robust pipeline of small molecule kinase inhibitors for the treatment of cancer, inflammatory disease and other indications. Ambit’s lead compound, quizartinib (AC220), is a novel, potent, highly selective, orally bioavailable FMS-like tyrosine kinase-3 (FLT3) inhibitor, and is currently under clinical investigation in

patients with relapsed or refractory AML and treatment-naïve AML. Ambit is developing quizartinib in collaboration with Astellas Pharma Inc. as part of a worldwide agreement to jointly develop and commercialize FLT3 kinase inhibitors in oncology and non-oncology indications. In addition to quizartinib, Ambit's clinical pipeline includes AC430, an oral JAK2 inhibitor, and CEP-32496, a BRAF inhibitor licensed to Teva. Ambit's preclinical portfolio includes a proprietary CSF1R inhibitor program. For more information, visit www.ambitbio.com.

About Astellas Pharma Inc.

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

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