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Singapore: Japan-headquartered Astellas Pharma and Ambit Biosciences have initiated the phase IIb open-label clinical trial of quizartinib as monotherapy in patients with relapsed and refractory acute myeloid leukemia (AML) with FLT3-ITD mutations. The two companies are co-developing Quizartinib, formerly AC220, which is a novel, potent, highly selective, orally bioavailable FMS-like tyrosine kinase-3 (FLT3) inhibitor.

The trial will enroll 64 adult patients (the estimated enroll of the protocol) in the US and Europe to evaluate two oral doses of quizartinib in 28-day cycles. The co-primary endpoints of the study are the composite complete response rate, complete remission with incomplete platelet recovery and complete remission with incomplete hematologic recovery, and 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 II 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).

"AML is amongst the most challenging hematological malignancies to treat, and very few treatment advances have been made in several decades," said Dr Jorge Cortes, 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."