A Phase 1/2, Multi-Center, Dose-Escalating Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Quizartinib Administered in Combination with Re-Induction Chemotherapy, and as a Single-Agent Continuation Therapy, in Pediatric Relapsed/Refractory AML Subjects Aged 1 Month to < 18 Years (and Young Adults Aged up to 21 Years) with FLT3-ITD Mutations (Protocol Number: AC220-A-U202/ADVL1822)

Status: Recruiting

Eligibility Criteria

Conditions & Interventions

More Information

Description: This is an open-label, multi-center, single arm, Phase 1/2 study to evaluate the safety, PK, PD, and efficacy of quizartinib administered in combination with fludarabine and cytarabine (FLA) (Re-Induction Cycles 1 and 2) chemotherapy for re-induction, with optional consolidation chemotherapy, and as a single agent continuation therapy (after optional, but strongly encouraged, HSCT per standard of care), in pediatric relapsed/refractory AML subjects aged ≥1 month old to <18 years old (and young adults up to 21 years old) with FLT3-ITD mutations.

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