NORTHSIDE HOSPITAL CANCER INSTITUTE
BLOOD & MARROW TRANSPLANT PROGRAM

The Blood & Marrow Transplant Group OF GEORGIA

Blood & Marrow Transplant Program

Clinical Trial Opening | NSH 1182

A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML

One of the most common genetic lesions in AML is FLT3/ITD and is associated with an overall poor prognosis. Allogeneic transplant is less effective for FLT3/ITD AML than for other AML subtypes. Gilteritinib (ASP2215) is a novel small molecule pyrazinecarboxamide derivative with inhibitory activity against FLT3. This Phase 3 Astellas and BMT CTN sponsored study (NCT02997202) will determine if the addition of Gilteritinib post allogeneic transplant will have a greater relapse-free survival (RFS) than the placebo controlled study arm.

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PRIMARY OBJECTIVE

Compare RFS between participants with FLT3/ITD AML in CR1 who undergo transplant and are randomized to receive gilterinitib or placebo beginning after time of engraftment for a two-year period.

CRITERIA

Registration Inclusion Criteria	Recipient Exclusion Criteria
› Confirmed AML in CR1 › Not received more than 2 cycles of induction › Any donor source, any graft source, any conditioning regimen allowed › Presence of FLT3/ITD mutation at diagnosis	› Prior allo transplant › KPS <70% › QTcF >450msec › Uncontrolled infections › Prior malignancy with curative intent <5 years › Requires treatment with strong inducers of CYP3A4
Randomization Inclusion Criteria	**Randomization Exclusion Criteria**
› ≥30 days and ≤90 days from transplant › ANC ≥500 and platelets ≥20k in absence of transfusion within prior 7 days › Confirmed AML in CR1 › If has grade II-IV acute GVHD, must not be taking >0.5mg/kg of prednisone or equivalent	› Requires treatment with strong inducers of CYP3A4 › QTcF >450msec › Uncontrolled infections

If you have any questions, would like to discuss study logistics, or the eligibility of any patients, please contact Stacey Brown, NH BMT/Leukemia Clinical Research Manager, at **404-780-7965** or **stacey.brown@northside.com**.

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