Ruxolitinib vs Prednisone as First-line Therapy for cGVHD Needing Systemic Therapy

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Age ≥ 18 years. * Karnofsky performance status ≥60%. * Patients with a diagnosis of chronic GVHD per NIH diagnostic criteria5 who are in need for first systemic therapy as per treating physician's discretion, Overlap chronic GVHD will be allowed. * No new immune suppressive therapy added within preceding 2 weeks prior to study enrolment. * Able to take oral medications. * Participants must have adequate organ and marrow function as defined below: 1. absolute neutrophil count ≥1,000/mcL 2. platelets ≥30,000/mcL 3. Hemoglobin ≥ 7 g/dL 4. Bilirubin ≤ 3 times institutional upper limit of normal (ULN) unless attributable to GVH d. AST(SGOT)/ALT(SGPT) ≤5 × institutional ULN unless attributable to GVH e. creatinine clearance ≥30 ml/min * Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 4 months after completion of study drug administration. * Ability to understand and the willingness to sign a written informed consent document.

Exclusion Criteria:

* Previously treated with systemic immune suppressive therapy for chronic GVHD (where the indication for start of that systemic immune suppressive therapy was chronic GVHD). * Patients with clinically significant or uncontrolled cardiovascular disease, including unstable angina, acute myocardial infarction, or stroke within 6 months, New York Heart Association class III or IV heart failure will be excluded. * Relapse malignancy post- transplant. * Active hepatitis B, hepatitis C and HIV will be excluded. * Any uncontrolled infection at the time if enrollment will be excluded. * History of allergic reactions attributed to compounds of similar chemical or biologic composition to Ruxolitinib. * Participants with psychiatric illness/social situations that would limit compliance with study requirements. * Pregnant women and lactating women are excluded from this study because of the potential for teratogenic or abortifacient effects and an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with Ruxolitinib, breastfeeding should be discontinued if the mother is treated with Ruxolitinib. * Current or history of active Tuberculosis.

Conditions & Interventions

Interventions:
DRUG: Ruxolitinib, DRUG: Prednisone
Conditions:
Chronic Graft-Versus-Host Disease (cGVHD)

More Information

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