A Study to Evaluate Axatilimab and Corticosteroids as Initial Treatment for Chronic Graft-Versus-Host Disease

Status: RECRUITING

Eligibility Criteria

Age: 12 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* ≥ 12 years of age at the time of informed consent. * New-onset moderate or severe cGVHD, as defined by the 2014 NIH Consensus Development Project Criteria for Clinical Trials in cGVHD, requiring systemic therapy. * History of allo-HCT from any donor HLA type (related or unrelated donor with any degree of HLA matching) using any graft source (bone marrow, peripheral blood stem cells, or cord blood). Recipients of myeloablative, nonmyeloablative, or reduced-intensity conditioning are eligible. * Adequate hematologic function with ANC ≥ 0.5 × 109/L independent of growth factors for at least 7 days prior to study entry. * Willingness to avoid pregnancy or fathering children.

Exclusion Criteria:

* Received more than 1 prior allo-HCT. Prior autologous HCT is allowed. * Has overlap cGVHD, defined as simultaneous presence of features or characteristics of aGVHD in a patient with cGVHD. * Received more than 7 days of systemic corticosteroid treatment for cGVHD or unable to begin a prednisone dose ≥ 1.0 mg/kg per day (or methylprednisolone equivalent) for cGVHD. * Received previous systemic treatment for cGVHD, including extracorporeal photopheresis. * Systemic treatment with CNIs or mTOR inhibitors started within 2 weeks prior to C1D1. * Prior treatment with CSF-1R targeted therapies. * Active, uncontrolled bacterial, fungal, parasitic, or viral infection. * Evidence of relapse of the primary hematologic disease or treatment for relapse after the allo-HCT was performed, including DLIs for the treatment of molecular relapse. * History of acute or chronic pancreatitis. * Active symptomatic myositis. * History or current diagnosis of cardiac disease indicating significant risk of safety for participation in the study, such as uncontrolled or significant cardiac disease. * Severe renal impairment, that is, estimated CrCl \< 30 mL/min measured or calculated by Cockcroft-Gault equation in adults and Schwartz formula in pediatric participants, or endstage renal disease on dialysis. * Impaired liver function, defined as total bilirubin \> 1.5 × ULN and/or ALT and AST \> 3 × ULN in participants with no evidence of liver cGVHD. * Pregnant or breastfeeding. Other protocol-defined Inclusion/Exclusion Criteria may apply.

Conditions & Interventions

Interventions:
DRUG: INCA034176, DRUG: Placebo, DRUG: Corticosteroids
Conditions:
Chronic Graft-versus-host-disease
Keywords:
cGVHD

More Information

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