Navn
CPR:

Patient nr:_____

Inklusionskriterier

Kriterie	Beskrivelse	Ja	Nej	NA
1	Male or female, aged 18 years or older inclusive at the time of signing the ICF.			
2	Active, clinically diagnosed, moderate or severe cGVHD per NIH Consensus Criteria(Jagasia et al 2015; Appendix C): a. Moderate cGVHD: At least 1 organ (except lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1. b. Severe cGVHD: At least 1 organ with a score of 3, or lung score of 2 or 3. Note: Candidates who transition from active aGVHD to cGVHD without tapering off of corticosteroids (< 0.25 mg/kg per day methylprednisolone or equivalent) ± CNI are also eligible.			
3	Underwent 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.			
4	KPS score ≥ 60%.			
5	Evidence of myeloid and platelet engraftment, that is, ANC ≥ 1.0 × 109/L and platelet count ≥ 50 × 109/L. Note: Use of growth factor supplementation and transfusion support is allowed during the study; however, transfusion to reach a minimum platelet count for inclusion is not allowed within the 7 days before the screening laboratory assessment.			
6	Willingness to avoid pregnancy or fathering children based on the criteria below. a. Men must agree to take appropriate precautions to avoid fathering children (with at least 99% certainty) from screening through 90 days after the last dose of study drug(s)/treatment and must refrain from donating sperm during this period. Permitted methods that are at least 99% effective in preventing pregnancy (see Appendix A) should be communicated to the participants and their understanding confirmed. b. Women of childbearing potential must have a negative serum pregnancy test at screening and before the first dose on Day 1 and must agree to take appropriate precautions to avoid pregnancy (with at least 99% certainty) from screening through safety follow-up. Permitted methods that are at least 99% effective in preventing pregnancy (see Appendix A) should be communicated to the participants and their understanding confirmed. c. Women of nonchildbearing potential (ie, surgically sterile with a hysterectomy and/or bilateral oophorectomy OR ≥ 12 months of amenorrhea) are eligible.			

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Eksklusionskriterier:				
Kriterie	**Beskrivelse**	**Ja**	**Nej**	**NA**
1	Has received more than 1 prior allo-HCT. Prior autologous HCT is allowed.			
2	Has received more than 3 days/72 hours of systemic corticosteroid treatment for cGVHD.			
3	Has received any other systemic treatment for cGVHD, including ECP. CNIs initiated before randomization may be continued at the same or lower dose; topical/inhaled steroids are acceptable.			
4	Prior treatment with a JAK inhibitor within 8 weeks before randomization. Participants who received a JAK inhibitor for aGVHD are eligible only if they achieved CR or PR.			
5	Removed in Amendment 6.			
6	Presence of active uncontrolled bacterial, fungal, parasitic, or viral infection. Infections are considered controlled if appropriate therapy has been initiated and, at the time of screening, no signs of infection are present.			
7	Active HBV or HCV infection that requires treatment, or at risk for HBV reactivation (ie, positive HBsAg). Participants with negative HBsAg and positive total HBc antibody may be included if HBV DNA is undetectable at the time of screening. Participants who are positive for HCV antibody are eligible only if PCR is negative for HCV RNA. Participants whose immune status is unknown or uncertain must have results confirming immune status before enrollment. Prior serology results are acceptable for determining eligibility.			
8	Known HIV infection.			
9	Evidence of relapsed primary hematologic disease, or receipt of treatment for relapse after the allo-HCT was performed, including DLIs for the treatment of molecular relapse.			
10	Maintenance therapy for the primary hematologic disease started within 4 weeks before initiation of study treatment (Day 1) or plans to start maintenance therapy after Day 1.			
11	Corticosteroid therapy at doses > 0.25 mg/kg per day methylprednisolone or equivalent for any treatment other than the diagnosis of cGVHD within 7 days of randomization.			
12	Participants on mechanical ventilation or requiring oxygen support or FEV1 < 30%.			
13	History or current diagnosis of cardiac disease indicating significant risk of safety for participation in the study, such as uncontrolled or significant cardiac disease, including any of the following: a. Recent myocardial infarction (within 6 months before randomization). b. New York Heart Association Class III or IV congestive heart failure. c. Unstable angina (within last 6 months before randomization). d. Clinically significant (symptomatic) cardiac arrhythmias (eg, sustained ventricular tachycardia, and clinically significant second or third degree AV block without a pacemaker). e. Uncontrolled hypertension.			

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14	Cholestatic disorders, or unresolved sinusoidal obstructive syndrome/veno-occlusive disease of the liver (defined as persistent total bilirubin > 2 mg/dL, or abnormalities not attributable to GVHD and ongoing organ dysfunction).			
15	Creatinine clearance ≤ 30 mL/min measured or calculated by Cockcroft-Gault equation.			
16	Pregnant or breastfeeding women.			
17	Anticipated need for live (including attenuated) vaccines during the first year of study.			
18	Treatment with an investigational agent, procedure, or device within 30 days of randomization, or within 5 half-lives of the investigational product, whichever is longer.			
19	Known allergies, hypersensitivity, or intolerance to any of the study medications, excipients, or similar compounds.			
20	Inability or unlikeliness of the participant to comply with the dose schedule and study evaluations, in the opinion of the investigator.			
21	Any condition that would, in the investigator's judgment, interfere with full participation in the study, including administration of study drug/treatment and attending required study visits; pose a significant risk to the participant; or interfere with interpretation of study data. Clinically significant laboratory abnormalities requiring urgent treatment should be resolved before initiation of study treatment.			
22	Inability of the participant (or parent, guardian, or legally authorized representative) to comprehend the ICF or unwillingness to sign the ICF.			

Dato: _____/_____ 20____ Læge (underskrift): _____