

Supplementary materials

Supplementary table S1: Accelerated glucocorticoid taper by tiered entry

Time (Week)	Prednisone dose and tapering schedule		
Screening: -6 to -2*	30	20	10
0	30	20	10
1	25	17.5	9
2	22.5	15	8
3	20	12.5	7
4	17.5	10	6
5	15	9	5
6	12.5	8	5
7	10	7	4
8	9	6	4
9	8	5	3
10	7	5	3
11	6	4	2
12	5	4	2
13	5	3	1
14	4	3	1
15	4	2	0
16	3	2	
17	3	1	
18	2	1	
19	2	0	
20	1		
21	1		
22	0		

*subjects must be on stable dose of either 30 mg, 20 mg, or 10 mg for 2 weeks prior to baseline (week 0)

Supplementary table S2: Definitions of adverse events and serious adverse events

Adverse Event (AE)	<p>An adverse event (AE) will be defined as any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.</p> <p>Any abnormal laboratory test results (hematology, clinical chemistry, or urinalysis) or other safety assessments (e.g., ECGs, radiological scans, vital signs measurements), including those that worsen from baseline, and felt to be clinically significant in the medical and scientific judgment of the investigator.</p> <ul style="list-style-type: none"> Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency and/or intensity of the condition.
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	<ul style="list-style-type: none">• Signs, symptoms, or the clinical sequelae of a suspected interaction.• Signs, symptoms, or the clinical sequelae of a suspected overdose of either study treatment or a concomitant medication (overdose per se will not be reported as an AE/SAE unless this is an intentional overdose taken with possible suicidal/self-harming intent. This should be reported regardless of sequelae).• "Lack of efficacy" or "failure of expected pharmacological action" per se was not be reported as an AE or SAE. However, the signs and symptoms and/or clinical sequelae resulting from lack of efficacy will be reported if they fulfil the definition of an AE or SAE.
Serious Adverse Event (SAE)	<p>Defined according to 21CFR 312.32. A serious adverse event (SAE) is any untoward medical occurrence that at any dose</p> <ul style="list-style-type: none">• Results in death• Is life-threatening• Requires hospitalization or prolongs existing hospitalization• Is a congenital anomaly/birth defect• An important medical event may be considered an SAE when, based upon appropriate medical judgment, it may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above

Supplementary Table S3: Criteria for temporary and permanent discontinuation of study drug

Hold investigational product if the following laboratory test results occur:	Investigational product may be resumed when:	Permanent discontinuation of study drug
WBC count <2000 cells/ μ L	WBC count \geq 2500 cells/ μ L	Unprovoked venous thromboembolism
ANC <1000 cells/ μ L	ANC \geq 1200 cells/ μ L	
Lymphocyte count <500 cells/ μ L	Lymphocyte count \geq 750 cells/ μ L	GCA relapse with evidence of severe ischemic event (vision loss, stroke, critical limb ischemia)
Platelet count <75,000/ μ L	Platelet count \geq 100,000/ μ L	
eGFR <40 mL/min/1.73 m ² (from serum creatinine)	eGFR \geq 50 mL/min/1.73 m ²	
ALT* or AST >5 x ULN	ALT and AST return to <2 x ULN, and investigational product is not considered to be the cause of enzyme elevation	Two GCA relapses occur during the study period
Hemoglobin <8 g/dL	Hemoglobin \geq 10 g/dL	Study drug has been held for drug-related lab abnormality necessitating temporary interruption and the laboratory abnormality leading to temporary hold has not returned to a level at which the study drug can be resumed [by 4 weeks (28 days) for renal function (as determined by eGFR) or 6 weeks for the remaining lab parameters] from the date of the study drug being held
Symptomatic herpes zoster	All skin lesions have crusted and are resolving	
Severe infection that, in the opinion of the investigator, merits the study drug being discontinued	Resolution of infection	
<p>Abbreviations: ALT = alanine aminotransferase; ANC = absolute neutrophil count; AST = aspartate aminotransferase; eGFR = estimated glomerular filtration rate; IP = investigational product; ULN = upper limit of normal; WBC = white blood cell.</p> <p>*ALT was used for monitoring purposes. If abnormal, the AST was checked for further assessment of abnormalities. Alkaline phosphatase and total bilirubin were obtained if evidence of liver disease was present on ALT and/or AST to assess for need of drug interruption</p>		