RESPONSE CRITERIA APPENDIX C: Proposed calculations for partial response in chronic GVHD

Organ and Starting Score or Value	Partial Response Criterion*
Skin (percent of body surface)	
> 50	$e/s \leq 0.5$ and $e > 0$
25 – 50	$s - e \geq 25$ and $e > 0$
< 25	only CR; no PR possible
Eye (mm Schirmer's test)	
< 5 mm	$e - s \geq 5$ mm and $e <$ LLN
5 – 10 mm	only CR; no PR possible
Mouth (15-point Schubert scale)	
> 8	$e/s \leq 0.5$ and $e > 0$
4 – 7	$s - e \geq 4$ and $e > 0$
< 4	only CR; no PR possible
Platelet count	$e - s \geq 100,000$/uL and $e <$ LLN
Gastrointestinal (and other 0 – 3 scales)[†]	
3	$e = 1$ or 2
2	$e = 1$
1	only CR; no PR possible
Liver function tests (ALT, alkaline phosphatase and bilirubin) and eosinophil count	
$\geq$ 3x ULN	$e/s \leq 0.5$ and $e >$ ULN
< 3 x ULN	only CR; no PR possible

*s, starting score or value; e, ending score or value; ULN, upper limit of normal; LLN, lower limit of normal

[†]The proposed response criterion could be appropriate for shorter-term phase II studies. For longer-term pivotal phase III studies, a 1-point change might not be sufficient for PR.

Examples
1. Skin: start score = 85, end score = 30; $e/s = 30/85 = 0.35 =$ PR
2. Skin: start score = 65, end score = 45; $e/s = 45/65 = 0.75 =$ not PR
3. Skin: start score = 45, end score = 15; $s - e = 30 =$ PR
4. Skin: start score = 30, end score = 15; $s - e = 15 =$ not PR

RESPONSE CRITERIA APPENDIX D – Proposed calculations for progression in chronic GVHD

Organ and Starting Score or Value	Progression Criterion*
Skin (percent of body surface)	$e - s \geq 25$
Eye	$s - e \geq 5$ mm
Mouth (15-point Schubert scale)	$e - s \geq 3$
Platelet count	$s - e \geq 50,000$/uL and $e <$ LLN
Gastrointestinal (and other 0 – 3 scales)	$e - s \geq 1$
Liver (ALT, alkaline phosphatase and bilirubin), eosinophil count	
$s \geq 3$x ULN	$e - s \geq 3$ x ULN
$s < 3$x ULN	$e - s \geq 2$ x ULN
Lungs (12-point Lung Function Scale)	$e - s \geq 3$[†]

*s, starting score or value; e, ending score or value; ULN, upper limit of normal
[†]If the starting lung function score is ≥ 10, progression is defined as $\geq 5\%$ decrease of FEV_1 in two tests measured at least 2 weeks apart. This time interval was selected because these syndromes can progress rapidly.