

Appendix 2. Response Assessment Criteria (modified from Hallek et al. 2018)**Response Definition After Treatment for Patients with CLL**

Group	Parameter	CR	PR	PD	SD
A	Lymph nodes	None ≥ 1.5 cm	Decrease $\geq 50\%$ (from baseline) ^a	Increase $\geq 50\%$ from baseline or from response	Change of -49% to +49%
	Liver and/or spleen size ^b	Spleen size <13 cm; liver size normal	Decrease $\geq 50\%$ (from baseline)	Increase $\geq 50\%$ from baseline or from response	Change of -49% to +49%
	Constitutional symptoms	None	Any	Any	Any
	Circulating lymphocyte count	Normal	Decrease $\geq 50\%$ from baseline	Increase $\geq 50\%$ over baseline	Change of -49% to +49%
B	Platelet count	$\geq 100,000/\mu\text{L}$	$\geq 100,000/\mu\text{L}$ or increase $\geq 50\%$ over baseline	Decrease of $\geq 50\%$ from baseline secondary to CL	Change of -49% to +49%
	Hemoglobin	≥ 11.0 g/dL (untransfused and without erythropoietin)	≥ 11 g/dL or increase $\geq 50\%$ over baseline	Decrease of ≥ 2 g/dL from baseline secondary to CLL	Increase <11.0 g/dL or <50% over baseline, or decrease >2 g/dL
	Marrow	Normocellular, no CLL cells, no B-lymphoid nodules	Presence of CLL cells, or of B-lymphoid nodules, or not done	Increase of CLL cells by $\geq 50\%$ on successive biopsies	No change in marrow infiltrate

CLL=chronic lymphocytic leukemia; CR=complete response; CT=computed tomography; PD=progressive disease; PR=partial response; SD=stable disease.

Note: CR, complete remission: all of the criteria have to be met; PR, partial response: for a PR at least 1 of the parameters of group A and one parameter of group B need to improve if previously abnormal. If only one parameter of both groups A and B is abnormal prior to therapy, only one needs to improve. PD, progressive disease: at least one of the above criteria of group A or group B has to be met; SD, stable disease: all of the above criteria have to be met. Constitutional symptoms alone do not define PD.

- Sum of the products of 6 or less lymph nodes (as evaluated by CT scans and physical examination in clinical trials, or by physical examination in general practice).
- Spleen size is considered normal if <13 cm. There is not firmly established, international consensus of the size of a normal liver; therefore, liver size should be evaluated by imaging and manual palpation in clinical trials and be recorded according to the definition used in a study protocol.

For a detailed description of the response parameters see [Hallek et al. 2018](#).