

Further thoughts about the ILLUMINATE studies of tabalumab in SLE

Chiche and colleagues make some very pertinent comments about the apparent failure of Tabalumab (in the ILLUMINATE trials) set against the 'deemed' success of Benlysta (in the BLISS trials) when in fact an analysis of the results indicates that there is little to choose between them.

I would point out that the least successful of these four trials, ILLUMINATE 1, was not helped by the decision made by the company to consider patients who changed their concomitant dose of steroids to have failed the trial even if that change was a reduction in the steroids. The authors also suggest that the failure to 'label', that is, approve, Benlysta in the UK was because its effects were too modest. This was indeed part of the issue but the other aspect was the very high price (around \$30 000 per patient per annum).

They further propose that B-lymphocyte stimulator (Blys)/B-cell activating factor (BAFF) levels at baseline are insufficient to define likely responders to B cell targeted therapy. My colleagues and I have pointed out elsewhere¹ that a group of patients with SLE responds to rituximab with a rapidly rising BLYS level which has led us to propose a trial in which rituximab followed by Benlysta will be evaluated (BEAT-lupus). In my opinion it is often clinical trial design which mitigates against success in SLE clinical trials. I think, in particular, that unreasonable targets—setting the bar too high, coupled with an

excess of steroids and immunosuppressives used have made it very hard indeed for primary end points to be achieved.

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Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.



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To cite Isenberg D. *Ann Rheum Dis* 2016;**75**:e11.

Received 5 October 2015

Accepted 10 October 2015

Published Online First 3 November 2015



► <http://dx.doi.org/10.1136/annrheumdis-2015-208702>

Ann Rheum Dis 2016;**75**:e11. doi:10.1136/annrheumdis-2015-208709

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