Reviewer's report

Title: Novel therapeutic agents in clinical development for SLE

Version: 1 Date: 23 December 2012

Reviewer: George Bertsias

Reviewer’s report:

This is a well-written review article dealing with novel therapeutic agents which are currently in clinical development for SLE. I have no major comments.

Minor Essential Revisions

1. Belimumab has not been approved by some local administrations, including the NICE and the German drug administration. This deserves some discussion.

2. Some preliminary results on IFN-alpha blockade in SLE were published in the ACR 2012 meeting. The authors could discuss them.

3. Jak kinases and other small molecules/kinase inhibitors are also evaluated as therapeutic targets in SLE. The authors should report on their current status in clinical development in lupus or other autoimmune diseases.

4. Quite a few trials were terminated due to increased risk of serious infections. This should be emphasized at the Discussion.

5. How do the authors envision the use of these new biologic agents in the management of lupus? This is especially important in view of the results of the belimumab trials showing only modest clinical benefit that takes time to achieve. With the exception of B-cell depleting agents, will other agents be suitable as induction or as maintenance regimens? Or, is it that they will be used to minimize residual disease activity and/or exposure to steroids?

6. Table 1. I would add a separate column to define the type of lupus (ie, nephritis, general SLE) that is targeted in each trial.

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests