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Letter in support of NICE approval for idelalisib in double refractory follicular non-Hodgkin Lymphoma

Dear Sir / Madam,

We are writing to encourage the NICE STA committee to approve the use of idelalisib in double refractory follicular lymphoma. Although follicular lymphoma is an indolent lymphoma with excellent survival for the majority of patients, it is increasingly recognised that there are a group of patients who have poor outcomes and will die of their disease. Much recent work has identified the so-called 'Progression of disease within 24 months of treatment initiation' or POD24 risk factor as a critical determinant for survival. For these patients the 5-year overall survival rate is only approximately 50% [1]. This emphasises the consistent finding in follicular lymphoma that short remissions following R-chemo are associated with high risk disease.

The 101-09 study (which included a significant number of patients from England) investigated idelalisib in a very high-risk group of patients – those who were refractory to both rituximab and an alkylating agent. As these patients were a high-risk relapsed group, one would expect them to be higher risk that the POD24 group described above, who were a group of patients at first relapse. They therefore represent a small group of patients with high unmet need. However, the long-term follow-up from the 101-09 study shows a median overall survival of 5 years which is much better than expected. Furthermore, the median PFS for the participants receiving idelalisib was longer than their prior line of treatment which is unusual in follicular lymphoma where remissions are usually thought to shorten with time[2].

Furthermore, we collected the real-world results from UK patients treated with idelalisib when it was available on a named patient basis [3]. Although the baseline characteristics of the patients were of course different from those in the 101-09 study, the results were very similar, suggesting that there was benefit outside of a clinical trial setting. We are also very concerned that England is the only country in Europe which cannot access this agent. Although we are aware NICE only covers England, there is clearly a UK wide inequality of access for this agent, which is of great concern as it seems deeply unfair that, for example, a patient living in Edinburgh can be treated with idelalisib whereas as a patient in Newcastle cannot be.

We are very grateful for your time in reading this letter and considering our arguments. We are also very grateful for the excellent work of NICE and its committees.

Yours faithfully,

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Dr Rebecca Auer, Consultant haemato-oncologist, St Bartholomew's Hospital, London
Dr Mary Gleeon, Consultant Haemaologist, Guys and St Thomas' Hospital, London
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Dr Tobias Menne, Consultant Haematologist, Freeman Hospital, Newcastle
Professor Andy Davies, Honorary consultant medical oncologist, Southampton University Hospital
Professor Simon Rule, Professor of Haematology, Peninsula Medical School, Plymouth

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3. Eyre TA, Osborne WL, Gallop-Evans E, et al. Results of a multicentre UK-wide compassionate use programme evaluating the efficacy of idelalisib monotherapy in relapsed, refractory follicular lymphoma. *Br. J. Haematol.* 2017;181(4):555–559.