National Institute for Health and Care Excellence

Health Technology Evaluation

Fedratinib for treating disease-related splenomegaly or symptoms in myelofibrosis (Review of TA756) (ID5115)

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	GlaxoSmithKline	No comment	N/A
Wording	GlaxoSmithKline	No comment	N/A
Additional comments on the draft remit	GlaxoSmithKline	No comment	N/A

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	GlaxoSmithKline	No comment	N/A
Population	GlaxoSmithKline	No comment	N/A
Subgroups	GlaxoSmithKline	No comment	N/A
Comparators	GlaxoSmithKline	It is our understanding that Fedratinib is being appraised for treating disease-related splenomegaly or symptoms of primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis in adults only if they have previously had ruxolitinib. Therefore, GSK does not consider the list of comparators for patients who have not been treated with a JAKi treatment relevant for this scope consultation exercise. However, if the comparators for these patients are to be considered, GSK considers that momelotinib would treat patients with splenomegaly and/or symptoms of myelofibrosis who have not been treated with a JAKi treatment (i.e., no previous treatment with ruxolitinib and intermediate-2 or high-risk disease). The list of comparators in the draft scope lists only ruxolitinib for people eligible for treatment with ruxolitinib. Momelotinib has met its primary endpoint of non-inferiority to ruxolitinib with respect to Splenic Response Rate (SRR) at week 24 and demonstrated similar clinical efficacy in the SIMPLIFY-1 trial.1 Therefore, GSK believes an appropriate list of comparators for people eligible for treatment with ruxolitinib is as follows: • ruxolitinib. • momelotinib (subject to NICE evaluation)	Thank you for your comment. The marketing authorisation for people “who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib”. It is not restricted to people only if they have previously had ruxolitinib. The scope has been updated to include momelotinib (subject to NICE evaluation) for people whose disease has not been treated with a JAK inhibitor.

Section	Consultee/ Commentator	Comments [sic]	Action
Outcomes	GlaxoSmithKline	No comment	N/A
Equality	GlaxoSmithKline	No comment	N/A
Other considerations	GlaxoSmithKline	No comment	N/A
Questions for consultation	GlaxoSmithKline	No comments	N/A
Additional comments on the draft scope	GlaxoSmithKline	No comment	N/A

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

Leukaemia Care
MPN Voice
Novartis