MYL-1402O: Adis Evaluation

Clinical Considerations

- Biosimilar to reference bevacizumab
- Equivalent efficacy and tolerability to reference bevacizumab in patients with stage IV non-squamous NSCLC
- Similar pharmacokinetic and pharmacodynamic properties to those of reference bevacizumab
- MYL-1402O (as Abevmy®) is approved for all indications for which reference bevacizumab is approved

Summary

MYL-1402O (Abevmy®, Lextemy®) is a biosimilar of the reference anti-vascular endothelial growth factor antibody bevacizumab. Abevmy® is approved for use in all indications for which reference bevacizumab is approved, including the treatment of non-small cell lung cancer (NSCLC) and other solid cancers. Lextemy® is approved for all indications as reference bevacizumab, except in recurrent ovarian cancer.

MYL-1402O has similar physicochemical and pharmacodynamic properties to those of reference bevacizumab, and the pharmacokinetic similarity of the agents has been shown in healthy male subjects.

MYL-1402O demonstrated clinical efficacy equivalent to that of reference bevacizumab in patients with non-squamous NSCLC. The tolerability, safety and immunogenicity profiles of MYL-1402O were consistent with those of reference bevacizumab.

The role of reference bevacizumab in the management of solid cancers is well established and MYL-1402O provides an effective biosimilar alternative for patients requiring bevacizumab therapy.