

Tab 3 Draft Discussion Points

1. Discuss the design and conduct of the US and European Phase 3 studies
2. Discuss the evidence of efficacy and their validity
3. Discuss the appropriateness of the proposed indication given the size of studies, inclusion/exclusion criteria, and type of cancers studied
4. Discuss the risk (magnitude and severity) of anaphylactic/anaphylatoid reaction, and recommend the strategies that might mitigate the risk
5. Discuss the risk and benefit profile of Combidex for the proposed indication. If the proposed indication is not appropriate, please discuss whether there is a patient population where the benefit and risk profile is favorable.