FDA Briefing Document Addendum/Clarification

Oncologic Drugs Advisory Committee Meeting

April 28, 2023

FDA clarifies that while sensitivity analyses were pre-specified based on HRR biomarker status for the rPFS endpoint in PROpel, these analyses were not alpha-controlled. Further, the FDA concerns are focused on the patient population without tumor *BRCA* mutations; no analyses by tumor *BRCA* mutation status in PROpel were pre-specified, nor alpha-controlled.