

ISSUES FOR ODAC CONSIDERATION

1. In the E2100 study, PFS is clearly not a surrogate endpoint for survival in first line breast cancer. Can PFS be considered a measure of direct clinical benefit in initial treatment of metastatic breast cancer?
2. Is an estimated 5.5 month improvement in median PFS, with no improvement in survival, at a cost of increased toxicity and death, sufficient to establish a net clinical benefit in support of approval of bevacizumab for the initial treatment of patients with metastatic breast cancer?