Hot Topic: EMBRACA results

Capping off this year’s general sessions, Dr. Jennifer Litton presented the results of EMBRACA, a randomized, 2-arm phase 3 trial comparing the efficacy and safety of talazoparib (TALA) with standard single-agent physician’s choice of therapy (PCT) in patients with advanced breast cancer (aBC) and a BRCA germline mutation.

Talazoparib (TALA) is a highly potent dual-mechanism PARP inhibitor. The phase 1 trial established a tolerable dose of 1mg/day taken orally for continuous dosing, while the phase 2 ABRAZO trial showed efficacy and safety in patients with germline BRCA 1/2 mutations and prior platinum therapy or ≤3 prior cytotoxic regimens.

For EMBRACA, an international, open-label study, 431 patients were randomized 2:1 (TALA:PCT) and stratified by the number of prior chemotherapy regimens, tissue receptor status, and history of central nervous system metastases. Note that PCT (capecitabine, eribulin, gemcitabine, or vinorelbine) included oral and IV chemotherapy options. The primary objective was progression-free survival (PFS) assessed by blinded independent central review. Secondary objectives were ORR (objective response rate), CBR24 (clinical benefit rate at 24 weeks), OS (overall survival), and safety. Exploratory objectives included quality of life (QoL) outcomes and DOR (duration of response). The protocol-specific PCT was determined prior to randomization for each patient, with 44% selecting capecitabine and 40% eribulin.

Results presented PFS by blinded central review with a hazard ratio (HR) of 0.54 that is statistically significant. The one-year PFS was 37% in TALA vs 20% in PCT with a median follow-up time of 11.2 months. In the subgroup analysis, all subgroups favored TALA. In a pre-planned interim OS analysis that was planned if the primary endpoint was positive, HR favored TALA at 0.76 but did not yet reach statistical significance. There were higher percentages of complete and partial responses in patients who received TALA. For ORR for patients with measurable disease, the odds ratio was 4.99 that was statistically significant. CBR24 in the intention-to-treat population had an odds ratio of 4.28, which was also statistically significant. DOR by investigator assessment presented a 1-year probability of sustained response of 23% TALA vs 0% PCT.

Data on safety presented anemia as the primary adverse event (AE) for TALA, while the rate of neutropenia was higher in patients on PCT. For nonhematologic toxicities, fatigue, nausea, and headache were most commonly seen, and all were mostly grade 1. In summary of AEs, results were similar between the two arms with a small percentage resulting in a permanent drug discontinuation. Patients who received TALA had an improvement in their patient-reported global health status (GHS)/QoL vs patients randomized to PCT, where a deterioration was seen.

In conclusion, TALA resulted in significantly prolonged PFS by blinded central review in HER2-negative aBC patients with BRCA mutations in comparison

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to PCT, QRR and CBR24 all demonstrated a benefit with TALA. GHS/QOL showed a statistically significant overall mean change from baseline for those on TALA and a statistically significant delay in the time to clinically meaningful deterioration in patients receiving TALA. Lastly, TALA was generally well-tolerated with nonhematologic toxicity and few AEs resulting in treatment discontinuation.

Dr. Singh concluded by highlighting signs of progress toward evaluating safety and optimizing breast therapy for older patients. Efforts of the FDA, Friends of Cancer Research, and American Society of Clinical Oncology to modernize eligibility criteria for older adults in clinical trials, use of patient-reported outcomes to help inform about tolerability of therapy, and acquisition of real-world data from more diverse oncology practice settings all help inform efficacy and safety of novel treatments in older patients.

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