A MULTICENTER PHASE II TRIAL OF NAB-PACLITAXEL IN COMBINATION WITH CAPECITABINE IN PATIENTS (PTS) WITH HER-2 NEGATIVE AND TRIPLE NEGATIVE ADVANCED BREAST CANCER (ABC): AN INTERIM ANALYSIS

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Aim: ABC remains a therapeutic challenge in spite of the use of emerging new drugs. Nab-paclitaxel has better efficacy and no risk of hypersensitivity reactions when compared to paclitaxel. We studied the association of nab-paclitaxel and capecitabine in a novel schedule as a line treatment in a population of HER-2 negative and triple-negative ABC. An interim analysis was planned at 54 enrolled pts.

Methods: Nab-paclitaxel 150 mg/m² was administered day 1 and 8 out of 21 days in combination with capecitabine at 825 mg/m² twice daily, day 1-14 out of 21 days as first-line therapy for HER2 negative ABC. The primary endpoints of the study are response rate (RR) and progression-free survival (PFS), secondary endpoints are toxicity and overall survival (OS).

Results: Sixty-five pts were enrolled from 11 centers, 59 pts (90.8%) evaluable for RR and PFS (ITT), 58 pts evaluable (89.3%) for toxicity. Median age was 56 years (34-77), 21 (32.3%) pts had triple-negative ABC, 44 pts (67.7%) hormone receptor positive ABC. Median number of metastatic site was 2 (range 1-5), visceral disease was present in 48 pts (73.9%). Median number of cycles was 6 (range 1-8). CR were 4 (6.8%), PR 31 (52.5%), for an overall RR (ORR) of 59.3%. SD was observed in 15 pts (25.4%), PD in 9 pts (15.3%). In the subpopulation of triple negative ORR was 50%. Median PFS for all pts was 43 weeks (26-48), 25 weeks (11-37) in triple-negative pts. Hematological toxicity Grade 3/4 was seen in 12/3 pts (18.5%/4.6%) (neutropenia G3/4 10/1 pts (15.4%/1.5%) and febrile neutropenia 2 pts (3%), respectively). Non-hematological toxicity grade 3/4 was seen in 11/10 pts (17%/15.4%), particularly neuropathy G3/4 1/0 (1.5%/0%).

Conclusions: Significant clinical activity and good tolerability was seen from the combination of nab-paclitaxel and capecitabine in HER-2 negative ABC. The study is ongoing, but data provide a basis to consider this regimen for further evaluation in phase III trials.

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