breast cancer, metastatic

**VINFLUNINE (VFL) PLUS CAPECITABINE (CAPE) FOR ADVANCED BREAST CANCER (ABC) PREVIOUSLY TREATED WITH OR RESISTANT TO ANTHRACYLINE AND RESISTANT TO TAXANE: A PHASE 3 STUDY VERSUS CAPECITABINE**


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**Aim:** VFL a microtubule inhibitor has demonstrated single-agent activity in ABC pretreated with anthracycline (A) and resistant to taxanes (T) and a synergy with CAPE in this setting. This phase 3 study compared VFL plus CAPE with CAPE alone in A-pretreated or -resistant and T-resistant ABC. An update of investigator’s assessed PFS and overall survival is presented.

**Methods:** Open-label, multicenter study, with 770 ABC patients with up to 3 prior chemotherapy (CT) regimens randomised to VFL 280 mg/m² on day 1 plus CAPE 1650 mg/m² (N = 384) or to CAPE alone at 2500 mg/m² (N = 386) on days 1 to 14 every 3 weeks. Randomization was stratified by resistance to anthracycline, performance status, disease measurability and number of prior lines of CT for ABC.

**Results:** Patients had a median age of 54 years (range: 27 - 81); metastatic disease for 97%; anthracycline resistance for 63%; received study treatment as 1st (20%), 2nd (48%) or > 3rd (32%) CT line for ABC. The median number of cycles was 6 for VFL plus CAPE and 5 for CAPE. VFL plus CAPE prolonged PFS assessed by IRC compared to CAPE (median 5.6 vs 4.3 months, HR = 0.84, 95% CI 0.71-0.99, P = 0.0426). This was supported by the investigator assessment (median 5.5 vs 4.1 months, HR = 0.77, 95% CI 0.66-0.90, P = 0.0007). The response rate assessed by IRC was numerically greater for VFL plus CAPE than for CAPE (22.9% vs 17.9%, P = 0.1030); the disease control rate was statistically superior with the combination (57.3% vs 47.9%, P = 0.0008). Median OS analysed after 674 deaths (87.5%) was 13.9 months for VFL plus CAPE and 11.7 months for CAPE (HR = 0.97, 95% CI = 0.83-1.14, P = 0.6976). The most frequent grade 3-4 events were neutropenia for VFL plus CAPE (27.2% of patients vs 6.6% for CAPE) and hand-foot syndrome for CAPE (18% vs 3.7% for VFL plus CAPE). Quality of life global health status score (QLQ-C30) was preserved for VFL plus CAPE while there was a deterioration for CAPE from week 12.

**Conclusions:** VFL plus CAPE demonstrates a statistically significant improvement in PFS both according to IRC and investigator and a trend towards better OS compared to CAPE alone. VFL plus CAPE is a new well tolerated option for A/T pretreated/resistant patients with ABC.

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