breast cancer, metastatic

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


1Medical Oncology Service, Hospital General Universitario Gregorio Marañón, Madrid, SPAIN
2Oncology, City Clinical Oncology Dispensary, Minsk, BELARUS
3Oncology, Dnipropetrovsk Medical Academy, City Multy-Field Clinical Hospital #4, Dnipropetrovsk, UKRAINE
4Oncology, Regional Antitumor Center, Donetsk, UKRAINE
5Oncology, Republican Clinical Oncology Dispensary, UFA, RUSSIAN FEDERATION
6Oncology, Kidwai Memorial Institute of Oncology, Bangalore, INDIA
7Oncology, Leningrad Regional Oncology Dispensary, St. Petersburg, RUSSIAN FEDERATION
8Oncology, Regional Clinical Oncology Dispensary, Arkhangelsk, RUSSIAN FEDERATION
9Medical Oncology Unit, Hôpital René Huguenin, Saint-Cloud, FRANCE
10Oncology, Centre Léon Bérard, Lyon, FRANCE
11Oncology, City Oncology Hospital, Kiev, UKRAINE
12Breast Cancer Unit, Department of Medical Oncology, Institut Gustave Roussy, Villejuif, FRANCE
13Oncology, Regional Oncological Hospital, Dnipropetrovsk, UKRAINE
14Oncology, North Estonia Medical Center, Tallinn, ESTONIA
15Oncology, Regional Clinical Oncology Dispensary, Utube, BELARUS
16Medical Oncology, CHU Bretagne, Tours, FRANCE
17Medical Oncology, Centre René Gauducheau, St Herblain, FRANCE
18Oncology, Clinique de Genolier, Genolier, SWITZERLAND

**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 = 0.0049). 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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