

| Study | Study type | No of patients | Study characteristics | Schedule | Median OS | Progression free survival/ median TTP | Overall Response rate |
|---|---|----------------|---|--|-------------|--|---|
| Freyer et al. JCO 2003 | Phase II, 1st line MBC | 64 | The median age of population was 63 years (35-79); 87.5% post-menopausal. 73% had at least two organs involved; 61% visceral disease. 1/3 had received prior adjuvant/neoadjuvant chemotherapy; anthracycline-based in most cases. | 80 mg/m2 weekly (after 3 administrations at 60) | 24 months | 4.2 months | 31% |
| Amadori et al. ECCO 2001 | Phase II, 1st line MBC | 72 | Open label, multi-center of patients treated between 1997 to 2000; median age of patients was 63 years; 23.6% stage IIIb or metastatic disease at diagnosis; 47.2% with visceral involvement and 57% with ≥ 2 organs involved. | 80 mg/m2 weekly (after 3 administrations at 60) | 21 months | 4.6 months | 27% |
| Blancas et al. ASCO 2010 | Phase II, 1st & 2nd line MBC | 45 | A multicentric Spanish trial evaluating PO vinorelbine as a single-agent in 1st or 2nd line. 53% hormone receptor positive, 90% had received adjuvant chemotherapy. 50% received treatment as 1st-line and 50% as 2nd line. | 80 mg/m2 weekly (after 3 administrations at 60) | NA | 4 months | 29.5% |
| Mansour et al. ICACT 2010 | Phase II, 1st line MBC; post-anthracycline +/- taxane | 26 | Oral vinorelbine evaluated in a population with unfavourable profile: 77% had at least 3 metastatic sites, 81% with visceral disease; previously treated with adjuvant anthracyclines +/- taxanes. | 80 mg/m2 d1,8 q3w (after 1 cycle at 60) | NA | 5 months | 42%; clinical benefit rate = 69% |
| Addeo et al. ASCO 2009 | Phase II, 1st line MBC | 32 | Italian multicentre study evaluated oral vinorelbine as a single agent, in the 1st line setting of elderly patients over the age of 70. Patients included had co-morbidities such as HT, DM, and COPD. | 80 mg/m2 weekly (fractionated at d1, 3, 5); 3 weeks on, 1 week off | 12.7 months | 7.1 months | 41% |
| Pluschnig et al. ESMO 2008 | Observational study | 100 | Single institution based Austrian study; observations from 100 consecutive patients. Most hormone positive and all of them were anthracycline resistant. 42% received PO Vinorelbine as 1st line, 36% as 2nd line, and 22% as 3rd or further line. 24% of patients were also HER2 positive and received Trastuzumab. | 60 mg/m2 d1,8 q3w | 17 months | 7 months | 26%; 4% complete RR; higher response when used 1st line |
| Garcia, PA et al. Eur J Cancer Supplements 2010 | Observational study; retrospective | 216 | International (seven countries), multicentre (13 centres) study evaluating oral vinorelbine either as a single-agent (54%) or in combination with capecitabine (46%) in 1st (56%) or 2nd line (44%) MBC between 2006-2008. Median age of patients was 61; 63% with hormone receptor positive disease; 49% with visceral metastases. In terms of prior treatments: 86% prior had prior chemotherapy (44% in the metastatic setting); 69% prior anthracyclines, 43% a prior taxane, and 38% both. | Dosing regimen not clearly stated | | 9.7 months 1st line; 6.6 months 2nd line; 7.1 months as single agent | Disease control rate = 74% as single-agent; 81% in combo 82% in 1st line, 71% in 2nd line |