resistance to aromatase inhibitor (AI) treatment in hormone receptor (HR) positive metastatic breast cancer (MBC).
Patients and Methods: Postmenopausal women with HR positive MBC received daily letrozole (2.5 mg orally) plus lapatinib (1,500 mg orally). Two cohorts of patients (pts) were studied: pts with primary resistant tumour who had a progressive disease as best response, or pts with secondary resistant tumour who had disease control followed by progression while they were receiving AI. The primary end point was objective rate response (ORR) at week 12. Secondary objectives included time to response, duration of response (DR), clinical benefit (CB), time to progression (TTP), overall survival (OS) and safety. Study was planned to enrol 110 pts in a 2 steps design. Accrual was closed prematurely at the time of planned interim analysis due to low recruitment.
Results: From January 2006 to December 2008, 28pts were enrolled. One patient was not evaluated due to consent withdrawn before treatment's initiation. Median age was 67.2 year old (range 34−93). All tumours were ER positive, 24 tumours were HER2 negative and the 3 HER2 positive are not included in the present analysis. A total of 7 pts reported a metastatic relapse under adjuvant treatment by AI, 18 (72%) pts had aprogressive disease under the first line of hormone therapy by AI for MBC. All cases analyzed were included in cohort 1 defined by secondary resistance to AI. The ORR at 12 weeks was 4% (95% CI: 0.7−20) (1complete response). Stable and progression disease were reported in 25% (95% CI 12−45) and 71% (95% CI 51−85) of cases respectively. At 24 weeks the ORR increased to 8% (95% CI 2−23). CB (responsive or stable disease >6 months) was 21% (95% CI 9−40). At a median follow up of 27 months, TTP and OS were 3.4 (95% CI 2.8−5.4) and 49.2 (95% CI 21.3- notreached) months, respectively.
The most common grade 1 or 2 (81% of pts)drug-related adverse events were diarrhea (41%), asthenia (30%), rash (26%), nausea and vomiting (22%), and mucositis (22%). Grade 3 or 4 drug-related adverse events were diarrhea (7%), rash(4%) and anorexia (4%). No cardiac toxicity was observed. Lapatinib was decreased at 1000 mg in 7% of pts and discontinuedin 7% of pts due to severe diarrhea.
Conclusion: This trial was prematured closed in November 2009 at the time of interim analysis. Interestingly, these preliminary results suggest that the addition of lapatinib to letrozole may be able to overcome tumoural resistance to AI in some pts with HER2 negative tumours.

5070 POSTER

Evaluation of Clinical Efficacy and Safety of Fulvestrant at a Dose of 500 mg in Patients With Metastatic Breast Cancer (MBC)

I. Blancas[1], M. Delgado[1], V. Conde[2], E. Gonzalez[2], A. Martínez[3], F. Rosillo[3]. *[1]Hospital Clinico San Cecilio, Oncology, Granada, Spain; [2]Hospital Virgen de las Nieves, Oncology, Granada, Spain; [3]Hospital Torrecardenas, Oncology, Almeria, Spain*

Background: The CONFIRM study has shown that fulvestrant (Faslodex®, F), an estrogen receptor (ER) antagonist, at a dose of 500 mg/monthly (mo) is more effective than the 250 mg-dose. Following this study results, the 500 mg/mo-dose was approved in Spain. This study collected real life data on F use at a dose of 500 mg/mo in Spanish patients (pts).
Objective: To evaluate Clinical Benefit Rate (CBR) of F in postmenopausal pts with hormone receptor-positive MBC previously treated.
Material and Methods: We retrospectively evaluated 44 pts with MBC treated with F at a regime of: 500 mg intramuscularly on day 0, then 500 mg on days 14 and 28 and every 28 days thereafter; F 500 mg/mo). Median age was 60 (34−89). Hormonal receptor status recorded in 40 of 44 pts (40/44): 37 pts (92.5%) ER+/PgR+, 3 pts (7.5%) ER+/PgR−. HER2+ (40/44) 11 pts (27.50%). P53 (34/44) is positive in 6 pts (17.65%), high Ki67 (33/44) in 8 pts (24.24%). No visceral metastases in 36/44 pts (81.8%) and visceral metastasis in 8/44 pts (18.2%). Median number of previous treatment regimens: 3 (1−8).
Results: Average of F500 doses administered was 16 (2−42). CBR (37/44) was 84.1%: 6/44 pts (13.6%) with complete response, 17/44 pts (38.6%) with partial response and 14 /44 pts (31.8%) with stable disease.
There was a significant trend of higher CBR in pts without visceral metastases compared to pts with visceral metastases (94.4% vs. 37.5% $p < 0.0001$). CBR was significantly higher in pts with a reduced Ki67 expression compared with pts with high Ki67 expression (100% vs 62.5% $p = 0.0103$). No significant differences in the CBR was observed between HER2 over expressed group and HER2 negative group (100% vs 75.86% $p = 0.1592$). The median time to progression (TTP) was 16.2 months (8.9, 23.1), in pts with clinical benefits was 20.3 months vs 4.1 months in pts without CB ($p < 0.0001$). Median overall survival has not been reached yet. Toxicities occurred in 15 pts (34.1%), more frequent toxicities were: local injection site pain in 6 pts, hot flushes in 6 pts and less frequent were gastrointestinal disorders and fatigue. Three pts (6.8%) died because of disease progression.
Conclusions: F500 shows a remarkable clinical benefit and acceptable TTP even in pts with previously treated MBC with a suitable toxicity profile.

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Oral Vinorelbine in Combination With Capecitabine as a First Line Treatment in Patients (pts) With Metastatic Breast Cancer (MBC) Previously Treated With Anthracyclines ± Taxanes − Preliminary Results of a Multicentric Phase II Trial in Egypt

A. Kandil[1], E. Hamada[2], M. Moawad[3], L. Ezz El Arab[3], H. Metwalli[4], M. Bathiouny[3], C. Mourad[5]. *[1]Alexandria University Hospital, Clinical Oncology Department, Alexandria, Egypt; [2]Cairo University Hospital, Oncology and Nuclear Medicine Department, Cairo, Egypt; [3]Ain Shams University Hospital, Oncology Department, Cairo, Egypt; [4]Menofia University Hospital, Oncology Department, Menofia, Egypt; [5]Pierre Fabre Oncology Middle-East, Medical Affairs, Beirut, Lebanon*

Background: Oral chemotherapy (CT) represents a step forward in the management of MBC with a growing use in this setting. In parallel to pts' preferences for oral drugs, Oral Vinorelbine (V) with Capecitabine (C) is an active full oral combination used for the treatment of Her2 negative MBC with response rates ranging from 48 to 70% in published phase II data. We are reporting preliminary results of a study evaluating efficacy and safety of Oral (V) +(C) as a first line treatment for MBC.
Methods: 37 pts were enrolled in 6 centers in Egypt between July 2009 and July 2010. Eligible pts were female⩾18 years with Her2 negative MBC (84%) or with extensive local recurrence (16%). All pts had measurable disease relapsing after (neo) adjuvant anthracycline ± taxane based treatment, WHO PS⩽2, adequate bone marrow, hepatic and renal functions and no adjuvant CT within the last 6 months.
Pts were treated with Oral (V) 60 mg/m^2 D1, D8 for the first cycle and thereafter 80 mg/m^2 D1, D8 in combination with(C) 825 mg/m^2 twice daily from D1 to D14, every 21 days for 6 cycles. Continuing treatment beyond 6 cycles was possible for pts not having progressive disease. Primary endpoint (EP) was TTP;secondary EPs were RR, OS and safety.
Results: Median age was 55 years [range 34−74];median WHO PS 1 [0−2]. Thirty pts (81%) were post-menopausal, with previous (neo)adjuvant anthracycline-based therapy in 77% and anthracyclines+taxane based in 19%. Median disease-free interval from end of previous CT was 2 years. 25(82%) pts had 2 or more metastatic sites; bone (46%),liver (35%) and lung (32%) being the most frequent sites.
A median of 6 [3−9] CT cycles were given with a total number of 205 cycles delivered. 27 (73%) of pts completed the 6 cycles of treatment. Objective tumour response was achieved in 20 pts (54%), including 6 complete (16%) and 14 partial responses (38%), 10 pts (27%) had stable disease.
Median TTP and median OS are not yet reached.
No WHO G4 toxicities were noted.1 pt (3%) developed G3 nausea-vomiting. G2 neutropenia was reported in 3(8%) of pts and G2 hand foot-syndrome in 5(13%) of pts.5 (14%) and 12 (32%) of pts developed G2 neuropathy and G2 diarrhea respectively.
Conclusions: Preliminary results show that oral (V) + (C) combination is effective and well tolerated in first line MBC pts previously treated with anthracyclines ± taxanes. Results achieved in this study are comparable to data reported in literature. Oral CT appears to be a valid alternative to I.V treatment.

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First-Line Bevacizumab (Bev) Combined With Paclitaxel (pac) in Older Patients (pts) Treated for HER2-Negative Metastatic Breast Cancer (mBC) in a Routine Oncology Practice Study

F. Foerster[1], B. Aktas[2], M. Geberth[3], B. Tschechne[4], A. Schneeweiss[5], C. Salat[6], H. Tesch[7], M. Welslau[8], M. Schmidt[9]. *[1]University of Applied Sciences Zwickau, Department of Economical Sciences, Zwickau, Germany; [2]University Hospital Essen, Department of Gynecology and Obstetrics, Essen, Germany; [3]SPGO-Mannheim, Department of Gynecology and Oncology, Mannheim, Germany; [4]Oncology Practice Dres. Tschechne Luft Jordan, Department of Oncology, Lehrte, Germany; [5]University of Heidelberg, National Center for Tumour Diseases, Heidelberg, Germany; [6]Oncology Practice Salat Stoetzer Hiller, Department of Oncology, München, Germany; [7]Oncological Practice Bethanien, Department of Oncology, Frankfurt, Germany; [8]Oncology Practice Dres. Welslau Klausmann, Department of Hematology/Onkology, Aschaffenburg, Germany; [9]University Hospital Mainz, Department of Obstetrics and Gynecology, Mainz, Germany*

Background: First-line Bev combined with weekly pac significantly improves progression-free survival (PFS) and response rate (RR) vs pac alone in HER2-negative mBC, as shown in E2100. The benefit of Bev