breast cancer, metastatic

ASSESSMENT OF TREATMENT RESPONSE WITH FULVESTRANT (F) 500 MG IN STANDARD CLINICAL PRACTICE THROUGH A RETROSPECTIVE STUDY: NCT01509625


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Aim: After CONFIRM study results, fulvestrant 500 mg (F500) became one of the standard treatments for patients with oestrogen receptor (ER+) Metastatic Breast Cancer (MBC) who previously had progressed on hormonal treatment. The aim of this study is to describe the efficacy of F500 in terms of progression free survival (PFS) and clinical benefit rate (CBR: complete response [CR] + partial response [PR] + stable disease [SD] ≥24 weeks [SD]) in Spanish patients (P) with oestrogen receptor (ER+) MBC, through a retrospective data collection

Methods: After written informed consent, data collection was recorded from clinical records of P who previously had progressed on hormonal treatment and who received at any time F 500 from 1st January 2010 to 30th June 2012. Preliminary results after 102 P were presented in 2013.

Results: 272 P in 25 centers were included in the study, 263 P were evaluable. Median age was 65.8 (56.3-72.2). Histology: 80.3% ductal; 14.3% lobulillar. Hormonal receptors: ER+ / PgR+ 76.1%; ER+ / PgR- 23.6%. HER2 status was documented in 232P, 11.2% of them were HER2+. 49.3% were Ki67 +. Mean time from diagnosis to metastatic disease: 3.7 years, 20.9% of P had de novo metastatic disease. 14.4% of P had visceral metastases and 88.8% had good PS (0-1) when F started. F was received as 1st line in 22.6%, as 2nd line in 32.2% and 3rd or more in 45.2% of the P. Average cycles administered: 13.7 (SD 11.1). With a median follow up of 16 months (m) since F treatment (1.4-34.4), median PFS was 10.6 m [9.0-11.5]. CBR was 56.5% (6.9% CR, 14.1% PR and 35.5% SD). Median PFS in P with or without CB was 18.4 m and 4.8 m respectively. Median PFS in P receiving F in 1st line was 11.5 m, 10.6 m in 2nd line and 9.9 m in 3rd line or more. No significant differences in CBR were observed between P with or without visceral metastases (52.8 vs 57.1%) or P with HER–ve and +ve tumours (57.1% vs 50.0%). Median Overall Survival was 43.2 m (37.0; NR). 1-year survival rate was 86.7%. More frequent toxicities were: local injection site pain (9.9%) joint disorders (7.2%) gastrointestinal disorders (6.8%) and hot flushes (6.1%).

Conclusions: F500 in real life setting showed a PFS of 10.6 m and achieved CB in more than a half of P with a good toxicity profile, in line with phase III trials. P with visceral metastases may benefit from F same as those with non visceral involvement.

Disclosure: All authors have declared no conflicts of interest.