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Coordinatore: Daniela Greto

Sicurezza ed efficacia di Enzalutamide nel trattamento del carcinoma della prostata metastatico castration-resistant (mCRPC): esperienza dell'Università di Firenze

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DEGLI STUDI
FIRENZE



INTRODUCTION

- **ENZALUTAMIDE:** non-steroidal competitive inhibitor of androgen receptor (AR) that acts on various steps inhibiting the binding of androgens to their receptor, the AR nuclear translocation and its interaction with DNA
- Prolongation of median OS of patients with mCRPC both pre that in post-chemotherapy setting



BACKGROUND

Enzalutamide in Men with Chemotherapy-naïve Metastatic Castration-resistant Prostate Cancer: Extended Analysis of the Phase 3 PREVAIL Study

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Increased Survival with Enzalutamide in Prostate Cancer after Chemotherapy

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MATERIAL AND METHODS (1)

- 20 pts (May 2013- April 2016) with mCRPC advanced after TXT

→ Enza 160mg die

- TAD with LHRH analogous (Agonists: 18pts – Antagonists: 2 pts)



MATERIAL AND METHODS (2)

PTS CHARACTERISTICS	
AGE (ys)	64 (Range:53-78) 73 (Range:56-85)
TUMOR STAGE, n (%)	II: 5 (25%) III: 15 (75%)
CARDIOVASCULAR COMORBIDITIES, n (%)	Yes: 12 (60%) No: 8 (40%)
Pre-ENZA PSA	141.06 ng/ml (Range: 2.08-1093 ng/ml)
Pre-CHT, n (%)	TXT: 20 (100%) Cabazitaxel: 2 (10%) Abiraterone: 9 (45%)
CONCOMITANT BISPHOSPHONATES, n (%)	Yes: 8 (40%) No: 12 (60%)





AIM of the STUDY

Outcomes and toxicity of patients with mCRPC treated with Enzalutamide

- Primary Endpoints :

1. Time to Radiological Progression(TTRP)
2. Time to Biochemical Progression(TTBP)
3. Time to first Skeletal Related Events (TTSRE)
4. Overall Survival (OS)

- Secondary Endpoints :

1. Adverse Events (AE)
2. PSA response



RESULTS (1)

- Median Follow up : 6.8 months (range 0.9-36.3)
- ✓ Enzalutamide: 6.5 median cycles (range: 2-13)
- ✓ 8 died pts
- ✓ 16 biochemical and radiological PD

	Median (months)	2ys
TTRP	13	55%
TTBP	8	45%
TTSRE	8	50%
OS	11	60%



RESULTS (2)

- 17 pts (85%): ↓ PSA
- 5/17 pts: ↓ PSA >50%

- ✓ Baseline PSA
- ✓ ↓ PSA >50%
- ✓ Hb > 10 g/dL

no association with TTRP and TTBP



RESULTS (3)

- Radiological Progression*: 10 pts (50%)
- Skeletal events: 10 pts (50%)
- Palliative RT for skeletal events: 5/10 pts (Range: 15-30Gy)

*Response Evaluation Criteria In Solid Tumors (*RECIST Criteria*)

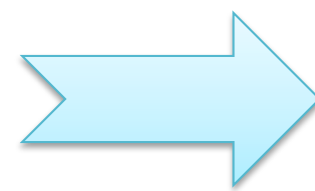


RESULTS (4)

Toxicity	n°
Astenia	12
Anemia	8
Cephalgy	2
PLT reduction	1 (G2)
IMA	1
TIA	1



No Tox
G3 and/o G4



Interruption



CONCLUSIONS



ENZALUTAMIDE: VALID OPTION in the treatment of mCRPC with a GOOD TOLERANCE PROFILE

Grazie per la Vostra attenzione

