

2401P
Combined treatment with radium-223 (RAD) and enzalutamide (ENZ) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC): Insights from the global REASSURE study

I. Jan de Jong¹, C.N. Sternberg², S. George³, D.Y. Song⁴, P.S. Conti⁵, S. Dizdarevic⁶, D. Heinrich⁷, J.P. Sade⁸, J. Meltzer⁹, M.J. Korn¹⁰, O. Sartor¹¹, B. Tombal¹²

¹ Department of Urology, University Medical Center Groningen, Groningen, Netherlands, ² Meyer Cancer Center, New York-Presbyterian Hospital, Englander Institute for Precision Medicine, Weill Cornell Department of Medicine, New York, United States of America, ³ Department of Medicine, Roswell Park Comprehensive Cancer Center, Buffalo, United States of America, ⁴ School of Medicine, Johns Hopkins University, Baltimore, United States of America, ⁵ Molecular Imaging Center, Keck School of Medicine of USC, Los Angeles, United States of America, ⁶ University Hospitals Sussex NHS Foundation Trust, Brighton & Sussex Medical School, University of Sussex and Brighton, Brighton, United Kingdom, ⁷ Department of Medical and Radiation Oncology, Innlandet Hospital Trust, Gjøvik, Norway, ⁸ Department of Clinical Oncology, Alexander Fleming Institute, Buenos Aires, Argentina, ⁹ Medical Statistics, Bayer HealthCare Pharmaceuticals Inc., Whippany, United States of America, ¹⁰ Global Medical Affairs Dept., Bayer HealthCare Pharmaceuticals Inc., Whippany, United States of America, ¹¹ School of Medicine, Tulane University, New Orleans, United States of America¹² Division of Urology, Cliniques Universitaires Saint Luc, Woluwe-Saint-Lambert, Belgium

Background

ENZ and RAD both prolong overall survival (OS) in pts with mCRPC. PEACE III trial (NCT02194842) reported positive outcomes with combined ENZ/RAD treatment (tx). Here, we report outcomes of pts who received combined ENZ/RAD in a real-world setting using the global prospective REASSURE study (NCT02141438).

Methods

1,472 pts (ALL pts) were analysed, including a subgroup receiving combined ENZ/RAD (pts started RAD and ENZ within 30 days of each other, n=45). We report baseline characteristics (BL), short- and long-term safety for ENZ/RAD and ALL pts. Statistics were descriptive in nature.

Results

BL of ENZ/RAD were similar to ALL pts, except for shorter times from initial bone metastases and castration resistance diagnosis to study entry, and fewer pts had prior docetaxel (TABLE). Median number of RAD injections was 6 in ENZ/RAD and ALL pts. However, 73% of ENZ/RAD completed RAD tx vs only 60% in ALL pts. Treatment-emergent (TE) serious adverse events (SAEs) and TE drug-related AEs were observed in 20% and 36% of pts, respectively, similar to ALL pts. However, drug-related SAEs were slightly higher in ENZ/RAD (11%) while it was 6% in ALL pts. Concomitant bone protective agents (BPAs) included denosumab and zoledronic acid, which were received by 56% and 9% of ENZ/RAD pts, respectively; 7% experienced fractures. Incidence of fractures was slightly higher in ALL pts (10%) with fewer pts receiving concomitant BPAs (denosumab 28% and zoledronic acid 13%). Median OS was 19.3 months for ENZ/RAD pts and 15.6 months in ALL pts.Table: 2401P

| | ENZ/RAD (N=45) | ALL Pts (N=1,472) |
|---|----------------|-------------------|
| Median time since initial diagnosis of bone metastases to study entry, months | 14 | 23 |
| Median time since castration resistant cancer to study entry, months | 7 | 13 |
| Extent of disease, % | | |
| Bone only metastases | 80 | 81 |
| Bone metastases + lymph node only | 9 | 13 |
| Disease burden, % | | |
| <6 metastases | 22 | 19 |
| 6–20 metastases | 47 | 48 |
| >20 metastases but not Superscan | 18 | 20 |
| Superscan | 4 | 6 |
| Laboratory values, median | | |
| ALP (U/L) | 131 | 133 |
| PSA (ng/mL) | 33 | 59 |

| | ENZ/RAD (N=45) ALL Pts (N=1,472) | |
|-----------------------|----------------------------------|----|
| Prior abiraterone, % | 40 | 48 |
| Prior docetaxel, % | 16 | 39 |
| Prior Sipuleucel-T, % | 18 | 9 |

Conclusions

In this subgroup of pts treated with combined ENZ/RAD in a real-world setting, there was no new safety signal. Combination was well tolerated and most pts completed RAD. Pts received ENZ/RAD earlier in the disease course based on time from mCRPC, time from initial diagnosis of bone metastases and prior docetaxel. Fracture incidence was low in ENZ/RAD, and the majority of pts received BPAs.

Clinical trial identification

NCT02141438.

Editorial acknowledgement

Nick Davies, Bioscript.

Legal entity responsible for the study

Bayer Consumer Care, AG.

Funding

Bayer Consumer Care, AG.

Disclosure

I. Jan de Jong: Financial Interests, Personal, Speaker’s Bureau: AstraZeneca; Financial Interests, Personal, Other, Travel, accommodation or expenses: Bayer. C.N. Sternberg: Financial Interests, Personal, Advisory Board: Pfizer, MSD, AstraZeneca, Astellas, Sanofi, Genzyme, Roche-Genentech, BMS, Bayer, Foundation Medicine, Gilead, Medscape, UroToday, CCN Clinical, Janssen, NCI. S. George: Financial Interests, Personal, Advisory Role: Bristol-Myers Squibb, Bayer, Pfizer, Exelixis, Corvus Pharmaceuticals, Sanofi/Genzyme, EMD Serono, Seattle Genetics/Astellas, Eisai, Merck, AVEO, AstraZeneca, QED Therapeutics; Financial Interests, Institutional, Advisory Board: Pfizer, Merck, Agensys, Novartis, Bristol-Myers Squibb, Bayer, Eisai, Seattle Genetics/Astellas, Calithera Biosciences, Corvus Pharmaceuticals, Surface Oncology, Exelixis, Aravive, Aveo, Gilead Sciences. S. Dizdarevic: Financial Interests, Personal, Advisory Role: GE Healthcare, Bayer, Advanced Accelerator Applications. D. Heinrich: Financial Interests, Personal, Advisory Role: Astellas Pharma, Bayer, Eisai, Ipsen, Organon, Pfizer; Financial Interests, Personal, Other, Honoraria: Astellas Pharma, AstraZeneca, Bayer, Bristol-Myers Squibb, EUSA, Ferring, Ipsen, Janssen-Cilag, Merck, Sharp & Dome (MSD), Novartis, Novo Nordisk, Sanofi, Pfizer; Financial Interests, Institutional, Research Funding, Honoraria: AstraZeneca; Financial Interests, Institutional, Research Funding: Bristol-Myers Squibb, Eisai, Janssen-Cilag, MSD, Pfizer, Roche. J. Meltzer: Financial Interests, Personal, Full or part-time Employment: Bayer; Financial Interests, Personal, Stocks or ownership: Bayer, Pfizer, Lilly. M.J. Korn: Financial Interests, Personal, Full or part-time Employment: Bayer. O. Sartor: Financial Interests, Personal, Advisory Role: Bayer, Sanofi, AstraZeneca, Dendreon, Constellation Pharmaceuticals, Advanced Accelerator Applications, Pfizer, Bristol-Myers Squibb, Bavarian Nordic, EMD Serono, Astellas Pharma, Progenics, Blue Earth Diagnostics, Myovant Sciences, Myriad Genetics, Novartis, Clarity Pharmaceuticals, Fusion Pharmaceuticals, Isotopen Technologien, Janssen, Noxopharm, Clovis Oncology, Noria Therapeutics, Point Biopharma, TeneoBio, Telix Pharmaceuticals, Theragnostics; Financial Interests, Personal, Other, Travel, accommodation or expenses: Bayer, Johnson & Johnson, Sanofi, AstraZeneca, Progenics. B. Tombal: Financial Interests, Personal, Advisory Role: Astellas Pharma, Bayer, Ferring, Janssen, Takeda, Steba Biotech, Sanofi, Myovant Sciences, Pfizer/Astellas; Financial Interests, Personal, Speaker’s Bureau: Amgen, Janssen, Astellas Pharma; Financial Interests, Personal, Other, Travel, accommodation or expenses: Amgen, Astellas Pharma, Bayer, Ferring, Janssen, Sanofi; Financial Interests, Personal, Expert Testimony: Tookad; Financial Interests, Personal, Other, Honoraria: Amgen, Astellas Pharma, Bayer, Ferring, Sanofi, Janssen, Pfizer, Myovant Sciences; Financial Interests, Institutional, Research Funding: Ferring. All other authors have declared no conflicts of interest.