genitourinary tumours, prostate

SAFETY OF CABAZITAXEL + PREDNISONE (CBZ + P) IN PATIENTS (PTS) WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC) PREVIOUSLY TREATED WITH DOCETAXEL (DOC): COHORT COMPASSIONATE-USE PROGRAMME (CUP)


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Aim: In the Phase III TROPIC trial, Cbz + P improved survival vs. mitoxantrone + P in pts with mCRPC previously treated with DOC (P < 0.0001). A CUP was initiated to provide pre-licensing access to Cbz + P and assess real-world safety.

Methods: Cbz 25 mg/m² Q3W + P 10 mg QD were given until disease progression, death, unacceptable toxicity or physician/pt decision. Pts were followed for ≥30 days after last dose. Granulocyte colony-stimulating factor (G-CSF) was recommended in pts at risk of neutropenic complications.

Results: In total, 451 pts were enrolled in 12 countries (~70 sites) worldwide. Median age was 68 years (range 43–84), median time from last DOC to first Cbz + P dose was 4.4 months, and median cumulative last DOC dose was 675 mg/m². A total of 24.3% of pts progressed during last-line DOC. Most pts (90.0%) had ECOG performance status ≤1 and 59.9% had ≥2 metastatic sites. Median number of Cbz + P cycles was 5 (range 1–34). Treatment was discontinued due to progression in 40.0% and adverse event (AE) in 21.7%. Dose reductions (17.3%) and delays (36.4%) were due to related AEs in 15.3% and 15.7%, respectively. During the study, 248 pts (55.0%) received G-CSF, 214 (47.5%) at Cycle 1. In pts with prophylactic G-CSF use at Cycle 1 (n = 137, 30.4%), neutropenia and febrile neutropenia occurred in 4.4% and 0.7%, respectively; in pts without G-CSF at Cycle 1, respective rates were 7.6% and 1.7%. Treatment-emergent AEs (TEAEs) occurred in 83.4% (Grade 3/4 51.0%) and TEAEs related to treatment in 72.9% (Grade 3/4 41.2%). Most frequent Grade 3/4 TEAEs related to Cbz + P were neutropenia (16.9%), febrile neutropenia (8.9%), anemia (6.0%), leukopenia (5.1%) and fatigue (4.8%). 30 deaths (6.7%) occurred, due to progression, AE or other reasons during the on-treatment period (first dose – 30 days after last dose), or due to possibly related AEs during follow up.

Conclusions: In pts with prior taxane exposure, Cbz + P had a predictable, manageable safety profile consistent with the TROPIC trial. A low rate of neutropenic complications in pts with prophylactic G-CSF at Cycle 1 supports use of G-CSF to prevent haematological AEs in pts at risk.

Disclosure: A. Heidenreich: has provided a consultancy role and been a member of advisory boards for Astellas, Bayer, Janssen-Cilag, Sanofi Aventis, TEVA, and Dendreon, and has received research funding from Astellas and Sanofi Aventis. H. Ozen: has been a member of advisory boards for Sanofi, Astellas, Janssen and Bayer; W. R. Gerritsen: D has been a member of advisory boards for Sanofi, Astellas, Janssen and Bayer; R. Gerritsen: L.M. van Oort: has been a member of advisory boards for Sanofi, Astellas, Janssen and Bayer; W. R. Gerritsen: D has been a member of advisory boards for Sanofi, Astellas, Janssen and Bayer; J. Lee: has received research funding from Bayer; A. Boumessous: is an employee of Sanofi; Z. Su: is an employee and stock holder of Sanofi; S. Hitier: is an employee and stock holder of Sanofi. All other authors have declared no conflicts of interest.

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