Preliminary results of a phase II study of weekly cabazitaxel in "unfit" metastatic castration-resistant prostate cancer (mCRPC) patients progressing after docetaxel treatment (SOGUG-CABASEM trial)


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Aim: Cabazitaxel (C), a novel taxane developed to overcome docetaxel (D) resistance, showed an overall survival improvement after D in mCRPC in a three-weekly dose schedule. We aimed to evaluate efficacy and safety of a weekly C/prednisone (P) schedule in “unfit” mCRPC patients previously treated with D.

Methods: Unfit pts (ECOG 2, dose reduction due to febrile neutropenia during treatment with D or radiation therapy affecting more than 25% of bone marrow reserve) with mCRPC progressing after D treatment with adequate bone marrow, liver and kidney functions were included. C 10 mg/m² was administered on days 1, 8, 15 and 22 of 5-week cycles with P (5 mg b.i.d.). Radiological and PSA responses were evaluated according to the PCWG2 (Scher H, 2008) criteria and toxicity according NCI-CTC AE.

Results: To date 69 pts have been enrolled and data are available for 54. Median age was 73 y (range 54-83); 59% pts had ECOG 2, 83% had bone, 19% liver and 9% lung metastases. 50% had Gleason > 7. Twenty three pts (43%) achieved ≥50% PSA response and 19 (35.2%) ≥80% PSA response. Response was evaluable in 28 pts. PR was observed in 1 pt (3.6%) and SD in 18 pts (64.3%). Median PSA PFS was 5.9 months. Median overall survival was 8.3 months. Most frequent toxicities of all grades as percentage of pts were: anemia (44.4%), asthenia (22.2%), thrombocytopenia (27.8%), leukopenia (18.5%), diarrhea (11.1%), nausea (11.1%), neutropenia (5.6%), peripheral neuropathy (5.6%), and anorexia (3.7%). Grade 3-4: thrombocytopenia (20.4%), anemia (7.5%), leukopenia (3.8%), neutropenia (1.9%), asthenia (1.9%), diarrhea (1.9%), anorexia (1.9%), and peripheral neuropathy (1.9%). No grade IV diarrhea or febrile neutropenia was observed.

Conclusions: Administration of weekly C (10 mg/m²) plus P to unfit pts seems efficacious and safe with no grade 4 neutropenia, diarrhea or febrile neutropenia reported.

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