Abiraterone acetate plus prednisone versus placebo plus prednisone in chemotherapy-naive men with metastatic castration-resistant prostate cancer (COU-AA-302): final overall survival analysis of a randomised, double-blind, placebo-controlled phase 3 study

Abstract:

Abiraterone acetate plus prednisone significantly improved radiographic progression-free survival compared with placebo plus prednisone in men with chemotherapy-naive castration-resistant prostate cancer at the interim analyses of the COU-AA-302 trial. Here, we present the prespecified final analysis of the trial, assessing the effect of abiraterone acetate plus prednisone on overall survival, time to opiate use, and use of other subsequent therapies. In this placebo-controlled, double-blind, randomised phase 3 study, 1088 asymptomatic or mildly symptomatic patients with chemotherapy-naive prostate cancer stratified by Eastern Cooperative Oncology performance status (0 vs 1) were randomly assigned with a permuted block allocation scheme via a web response system in a 1:1 ratio to receive either abiraterone acetate (1000 mg once daily) plus prednisone (5 mg twice daily; abiraterone acetate group) or placebo plus prednisone (placebo group). Coprimary endpoints were radiographic progression-free survival and overall survival analysed in the intention-to-treat population. The study is registered with ClinicalTrials.gov, number NCT00887198. At a median follow-up of 49.2 months (IQR 47.0-51.8), 741 (96%) of the prespecified 773 death events for the final analysis had been observed: 354 (65%) of 546 patients in the abiraterone acetate group and 387 (71%) of 542 in the placebo group. 238 (44%) patients initially receiving prednisone alone subsequently received abiraterone acetate plus prednisone as crossover per protocol (93 patients) or as subsequent therapy (145 patients). Overall, 365 (67%) patients in the abiraterone acetate group and 435 (80%) in the placebo group received subsequent treatment with one or more approved agents. Median overall survival was significantly longer in the abiraterone acetate group than in the placebo group (34.7 months [95% CI 32.7-36.8] vs 30.3 months [28.7-33.3]; hazard ratio 0.81 [95% CI 0.70-0.93]; p=<0.0033). The most common grade 3-4 adverse events of special interest were cardiac disorders (41 [8%] of 542 patients in the abiraterone acetate group vs 20 [4%] of 540 patients in the placebo group), increased alanine aminotransferase (32 [6%] vs four [<1%]), and hypertension (25 [5%] vs 17 [3%]). In this randomised phase 3 trial with a median follow-up of more than 4 years, treatment with abiraterone acetate prolonged overall survival compared with prednisone alone by a margin that was both clinically and statistically significant. These results further support the favourable safety profile of abiraterone acetate in patients with chemotherapy-naive metastatic castration-resistant prostate cancer. Janssen Research & Development.
Urologische Klinik und Poliklinik

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