Abiraterone acetate improved overall survival in metastatic castration-resistant prostate cancer at a preplanned interim analysis of the COU-AA-301 double-blind, placebo-controlled phase 3 study. Here, we present the final analysis of the study before crossover from placebo to abiraterone acetate (after 775 of the prespecified 797 death events). Between May 8, 2008, and July 28, 2009, this study enrolled 1195 patients at 147 sites in 13 countries. Patients were eligible if they had metastatic castration-resistant prostate cancer progressing after docetaxel. Patients were stratified according to baseline Eastern Cooperative Oncology Group (ECOG) performance status, worst pain over the past 24 h on the Brief Pain Inventory-Short Form, number of previous chemotherapy regimens, and type of progression. Patients were randomly assigned (ratio 2:1) to receive either abiraterone acetate (1000 mg, once daily and orally) plus prednisone (5 mg, orally twice daily) or placebo plus prednisone with a permuted block method via an interactive web response system. The primary endpoint was overall survival, analysed in the intention-to-treat population. This study is registered with ClinicalTrials.gov, number NCT00091442.

Of the 1195 eligible patients, 797 were randomly assigned to receive abiraterone acetate plus prednisone (abiraterone group) and 398 to receive placebo plus prednisone (placebo group). At median follow-up of 20·2 months (IQR 18·4-22·1), median overall survival for the abiraterone group was longer than in the placebo group (15·8 months [95% CI 14·8-17·0] vs 11·2 months [10·4-13·1]; hazard ratio [HR] 0·74, 95% CI 0·64-0·86; p<0·0001). Median time to PSA progression (8·5 months, 95% CI 8·3-11·1, in the abiraterone group vs 6·6 months, 5·6-8·3, in the placebo group; HR 0·63, 0·52-0·78; p<0·0001), median radiologic progression-free survival (5·6 months, 5·6-6·5, vs 3·6 months, 2·9-5·5; HR 0·66, 0·58-0·76; p<0·0001), and proportion of patients who had a PSA response (235 [29·5%] of 797 patients vs 22 [5·5%] of 398; p<0·0001) were all improved in the abiraterone group compared with the placebo group. The most common grade 3-4 adverse events were fatigue (72 [9%] of 791 patients in the abiraterone group vs 41 [10%] of 394 in the placebo group), anaemia (62 [8%] vs 32 [8%]), back pain (56 [7%] vs 40 [10%]), and bone pain (51 [6%] vs 31 [8%]).

This final analysis confirms that abiraterone acetate significantly prolongs overall survival.
survival in patients with metastatic castration-resistant prostate cancer who have progressed after docetaxel treatment. No new safety signals were identified with increased follow-up.

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