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Cabazitaxel Versus Docetaxel As First-Line Therapy for Patients With Metastatic Castration-Resistant Prostate Cancer: A Randomized Phase III Trial—FIRSTANA

[Stéphane Oudard](#), [Karim Fizazi](#), [Lisa Sengeløv](#), [Gedske Daugaard](#), [Fred Saad](#), [Steinbjørn Hansen](#), [Marie Hjäl m-Eriksson](#), [Jacek Jassem](#), [Antoine Thiery-Vuillemin](#), [Orazio Caffo](#), [Daniel Castellano](#), [Paul N. Mainwaring](#), [John Bernard](#), [Liji Shen](#), [Mustapha Chadjaa](#), and [Oliver Sartor](#)

Stéphane Oudard, Georges Pompidou European Hospital, Rene Descartes University; Mustapha Chadjaa, Sanofi, Paris; Karim Fizazi, Institut Gustave Roussy, University of Paris Sud, Villejuif; Antoine Thiery-Vuillemin, Centre Hospitalier Universitaire Minjot Besançon, Besançon, France; Lisa Sengeløv, Herlev Hospital, Herlev; Gedske Daugaard, Copenhagen University Hospital, Rigshospitalet, Copenhagen; Steinbjørn Hansen, Odense University Hospital, Odense, Denmark; Fred Saad, Centre Hospitalier de l'Université de Montréal, Montréal, Quebec, Canada; Marie Hjäl m-Eriksson, Karolinska University Hospital, Stockholm, Sweden; Jacek Jassem, Medical University of Gdansk, Gdansk, Poland; Orazio Caffo, Santa Chiara Hospital, Trento, Italy; Daniel Castellano, University Hospital 12 de Octubre, Madrid, Spain; Paul N. Mainwaring, Icon Cancer Care, Brisbane, Queensland, Australia; John Bernard, Sanofi, Cambridge, MA; Liji Shen, Sanofi, Bridgewater, NJ; and Oliver Sartor, Tulane Cancer Center, New Orleans, LA.

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The Who, What, and How of Cabazitaxel Treatment in Metastatic Castration-Resistant Prostate Cancer
 Tian Zhang et al., *J Clin Oncol*
 Phase III Study Comparing a

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Purpose

In patients with metastatic castration-resistant prostate cancer (mCRPC), overall survival (OS) is significantly improved with cabazitaxel versus mitoxantrone after prior docetaxel treatment.

FIRSTANA ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01308567) identifier: NCT01308567) assessed whether cabazitaxel 20 mg/m² (C20) or 25 mg/m² (C25) is superior to docetaxel 75 mg/m² (D75) in terms of OS in patients with chemotherapy-naïve mCRPC.

Patients and Methods

Patients with mCRPC and Eastern Cooperative Oncology Group performance status of 0 to 2 were randomly assigned 1:1:1 to receive C20, C25, or D75 intravenously every 3 weeks plus daily prednisone. The primary end point was OS. Secondary end points included safety; progression-free survival (PFS); tumor, prostate-specific antigen, and pain response; pharmacokinetics; and health-related quality of life.

Results

Between May 2011 and April 2013, 1,168 patients were randomly assigned. Baseline characteristics were similar across cohorts. Median OS was 24.5 months with C20, 25.2 months with C25, and 24.3 months with D75. Hazard ratio for C20 versus D75 was 1.01 (95% CI, 0.85 to 1.20; *P* = .997), and hazard ratio for C25 versus D75 was 0.97 (95% CI, 0.82 to 1.16; *P* = .757). Median PFS was 4.4 months with C20, 5.1 months with C25, and 5.3 months with D75, with no significant differences between treatment arms. Radiographic tumor responses were numerically higher for C25 (41.6%) versus D75 (30.9%; nominal *P* = .037, without multiplicity test adjustment). Rates of grade 3 or 4 treatment-emergent adverse events were 41.2%, 60.1%, and 46.0% for C20, C25, and D75, respectively. Febrile neutropenia, diarrhea, and hematuria were more frequent with C25; peripheral neuropathy, peripheral edema, alopecia, and nail disorders were more frequent with D75.

Conclusion

C20 and C25 did not demonstrate superiority for OS versus D75 in patients with chemotherapy-naïve mCRPC. Tumor response was numerically higher with C25 versus D75; pain PFS was numerically improved with D75 versus C25. Cabazitaxel and docetaxel demonstrated different toxicity profiles, with overall less toxicity with C20.

Approved Dose (25 mg/m²) in Postdocetaxel Patients With Metastatic Castration-Resistant Prostate Cancer—PROSELICA

Mario Eisenberger et al., *J Clin Oncol*

Randomized, Double-Blind, Placebo-Controlled Phase III Trial Comparing Docetaxel and Prednisone With or Without Bevacizumab in Men With Metastatic Castration-Resistant Prostate Cancer: CALGB 90401

William Kevin Kelly et al., *J Clin Oncol*

First-Line Cabazitaxel vs Docetaxel in Metastatic Castration-Resistant Prostate Cancer

By Matthew Stenger, *The ASCO Post*

Prediction of favorable outcome in a docetaxel rechallenge setting in metastatic castration-resistant prostate cancer.

Matthias Michael Heck et al., *J Clin Oncol*

Pain Management for Advanced Breast Cancer
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Targeting androgen receptor and DNA repair in metastatic castration-resistant prostate cancer: Results from NCI 9012

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