

# Abiraterone acetate improves fatigue in prostate cancer patients, says international clinical trial

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Stockholm, Sweden: Men with prostate cancer that has spread to other parts of the body and that is resistant to hormone therapy suffer less from fatigue if they are treated with a combination of abiraterone acetate and prednisone, according to results from a phase III clinical trial presented today.

Dr Cora Sternberg told the 2011 European Multidisciplinary Cancer Congress, in Stockholm today (Monday 26 September), that the significant improvements in fatigue were important for this group of difficult-to-treat patients who had few available [therapeutic options](#).

"Metastatic castration-resistant prostate cancer is cancer that has spread from the prostate and that develops resistance to therapies targeting the [male sex hormones](#) such as [androgen](#) that drive the cancer's growth. It is a chronic, [progressive disease](#) and, until now, men have few treatment options and [poor prognosis](#). If treatment with androgen deprivation and docetaxel chemotherapy fails, then the average survival is only around 18-19 months," said Dr Sternberg, head of the Department of [Medical Oncology](#) at the San Camillo and Forlanini Hospitals in Rome, Italy.

"One of the most distressing issues these metastatic castration-resistant prostate cancer patients face during [hormone treatment](#) is [extreme fatigue](#). Our results show that abiraterone acetate therapy has the potential to reduce cancer-related fatigue in this patient population, in addition to the previously demonstrated [survival benefit](#)," she said.

Abiraterone acetate (ZYTIGA<sup>®</sup>) is a new oral drug that specifically blocks the production of the male sex hormones (androgens) by the prostate tumour itself, as well as the testes and adrenal

glands, all androgen sources which can fuel prostate cancer progression.

Dr Sternberg and her colleagues carried out a retrospective analysis assessing the effect of abiraterone acetate therapy on patient-reported fatigue using data from the COU-AA-301 international Phase III study. The study randomised 1195 patients with metastatic castration-resistant prostate cancer, who had previously received the chemotherapy drug [docetaxel](#), to receive the steroid prednisone with either abiraterone acetate (797 patients) or placebo (398 patients). Patient-reported fatigue was measured using the Brief Fatigue Inventory (BFI) questionnaire at various times during the study.

"We conducted a series of analyses to assess different aspects of the impact of abiraterone acetate on both fatigue intensity and interference with general activity, mood, walking, work, relationships and enjoyment of life," she said. "We also employed different analytical approaches to test our hypotheses. The results are clinically meaningful and remain robust after adjusting for non-random missing data."

The data indicated that patients who received abiraterone acetate had significantly better patient-reported outcomes for fatigue than the placebo group over the study duration. Indeed, the progression of fatigue intensity and interference with general activity, mood, walking, work, relationships and enjoyment of life was significantly delayed in patients who received abiraterone acetate.

At a later stage, Dr Sternberg and her colleagues are planning to explore potential associations between the improvements in patient-reported fatigue and other clinical variables such as overall

survival and disease progression.

Dr Sternberg added: "The future looks brighter for men with this disease and with several new therapies recently approved for advanced prostate cancer, we have more hope for our patients, because they are not only living longer, they are also living better. I think this is a huge step forward in the treatment of metastatic castration-resistant prostate cancer."

Cancer of the prostate is the second most commonly reported cancer in men, with more than 890,000 cases diagnosed worldwide every year. It usually occurs in older patients, and globally more than 250,000 men died from the disease in 2008.

"It is very important that research into new anti-cancer strategies not only evaluates its impact on prevention of tumour progression and improvement of survival time, but also evaluates in detail whether and how the treatment affects quality of life and the activity of patients," said Professor Michael Baumann, President of ECCO. "Severe fatigue is a very distressing side effect of some therapies against [prostate cancer](#) and research into therapeutic options leading to less fatigue is of great value for patients and their families."

Provided by ECCO-the European Cancer Organisation

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