Phase 3 trial confirms abiraterone acetate efficacy for patients with advanced prostate cancer

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Results of a phase 3 trial published in The *Lancet Oncology* have confirmed that the drug abiraterone acetate (marketed as Zytiga) offers a significant survival benefit to patients with castration-resistant prostate cancer, which is spreading to other parts of their body (known as metastatic prostate cancer).

Abiraterone works by blocking an enzyme involved in the production of testosterone, a hormone. Testosterone helps prostate cancer cells to proliferate, so blocking production of the hormone can reduce prostate cancer progression.

The study, which is the first phase 3 trial to show a significant survival benefit for a drug which works in this way, involved 1195 patients in thirteen countries, and compared the effects of prescribing abiraterone and the steroid prednisone, which combats some of the side effects of prostate cancer treatment, with a placebo plus predisnone.

The trial participants had all undergone at least one earlier round of chemotherapy with another drug, docetaxel, which had not halted the progression of their cancer. The researchers found that treatment with abiraterone acetate resulted in an average survival time of 15.8 months, compared to 11.2 months for those given a placebo.

For patients with metastatic prostate cancer, the average overall survival

time for patients who have undergone chemotherapy is consistently less than two years, so the increased survival time offered by abiraterone acetate could result in substantially improved prospects for patients whose prostate cancer continues to progress after initial treatment with docetaxel.

The trial also confirmed that abiraterone acetate appears to have a good safety profile; although some adverse events were recorded in patients given the drug, these were generally reversible, and didn't prevent continuation of the treatment.

According to one of the study's authors, Dr Karim Fizazi of the Institut Gustave Roussy in France, "Our work confirms that abiraterone acetate can be used as an effective and safe treatment for castration-resistant metastatic prostate cancer patients whose disease continues to progress after docetaxel treatment. Furthermore, unlike current alternatives for this patient population, abiraterone plus prednisone therapy can be given orally in an outpatient setting, providing an additional benefit for both patients and clinicians."

In a linked Comment, Dr Guru Sonpavde, the Director of Urologic Medical Oncology at the University of Alabama, Birmingham (UAB), Comprehensive Cancer Center, USA, welcomed the results, stating that "[This trial] represents an important advance in the therapy of metastatic castration-resistant prostate cancer," adding that, "[Further] clinical trials investigating novel drugs and combinations should be strongly encouraged since all available options are palliative in nature."

More information: www.thelancet.com/journals/lan … (12)70379-0/abstract

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