Abiraterone acetate improves survival in metastatic castration-resistant prostate cancer

October 12 2010

Patients with metastatic castration-resistant prostate cancer who have progressed after chemotherapy live significantly longer if treated with the drug abiraterone acetate compared to placebo, the results of a large Phase-III clinical trial confirm.

"This is a major step forward in prostate cancer therapeutics," said Dr Johann de Bono from The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust in London, who presented the study results at the 35th Congress of the European Society for Medical Oncology (ESMO) in Milan, Italy. "Patients in this Phase-III trial who received abiraterone had a median survival of four months longer than patients receiving a placebo."

"These results are likely to alter the standard of care for men with advanced prostate cancer who have progressed despite receiving docetaxel-based chemotherapy, a critically important area of unmet need," Dr de Bono said. "Men with metastatic castration-resistant prostate cancer have a poor prognosis, with only about one in three alive five years after diagnosis. For many men, abiraterone acetate can extend life."

Because the growth of prostate cancer is fuelled by the male hormone testosterone, reduction of the testosterone level in the body --for example through hormone therapy--can slow the tumor growth. But most

prostate cancers eventually become resistant to these treatments and resume growing.

Abiraterone acetate is designed to treat these tumors by inhibiting the production of androgen in the testes, the adrenal glands and prostate cancer tumors themselves. The Phase-III trial included 1195 patients from 13 countries whose metastatic, castration-resistant prostate cancer had previously been treated with one of two chemotherapeutic agents that included docetaxel.

Among the 398 patients randomly assigned to receive the corticosteroid prednisone plus placebo, median overall survival was 10.9 months. Among the 797 who received abiraterone acetate plus prednisone, median survival was 14.8 months.

Significant differences also emerged between the placebo and treatment groups for all of the trial's secondary endpoints, including time to prostate-specific antigen (PSA) progression, radiographic progression-free survival and PSA response rate.

The benefits of abiraterone were determined during a pre-specified interim analysis of the study, prompting the trial's Independent Data Monitoring Committee to recommend unblinding the trial, and allowing anyone on the placebo arm to be offered abiraterone acetate.

"Once we knew that the drug could prolong life for many patients, it was ethically critical that we made it available to all patients on the trial," Dr de Bono said.

The researcher noted that there were still some unanswered questions about abiraterone.

"A key question now is how to work out which patients will benefit from

the drug --clearly, some patients do and some don't. So although this is a significant advance, there is still a lot of work to do to improve outcomes for advanced prostate cancer."

Professor Carsten Bokemeyer, director of University Cancer Center Hamburg, Germany, commented that abiraterone acetate "is a true additional new treatment in prostate cancer."

"The results of this study show that the drug adds to the range of treatment options available for patients with advanced disease, with limited toxicity," Prof Bokemeyer said. "These results also challenge the current idea that there is no further treatment after chemotherapy for these patients. In fact, timing of hormone therapy and chemotherapy will become more complex and important in the future management of castration-resistant prostate cancer."

Provided by European Society for Medical Oncology