Apalutamide Delays Prostate Cancer Metastases by More Than Two Years

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Expert Perspective

“There is a population of men with prostate cancer who have no visible evidence of spread but who have a rise in their blood markers. These patients can have a poor prognosis, and until now, the optimal management of their cancer remained an enigma. These findings suggest there may finally be a treatment that holds real promise for extending their health and their lives,” said ASCO Expert Sumanta K. Pal, MD, moderator of today’s presscast.

ALEXANDRIA, Va. – Findings from the phase III placebo-controlled SPARTAN trial suggest that apalutamide is an effective treatment for men with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk for developing metastatic disease, and for whom no approved treatments exist. Men who received apalutamide had a 72% lower risk of metastasis or death than those who received placebo.

These findings, which according to the authors may be relevant to about 100,000 men in the United States, will be presented at the upcoming 2018 Genitourinary Cancers Symposium in San Francisco, California.

“Until this trial, there have been no drugs proven to benefit men with non-metastatic prostate cancer that has progressed despite standard hormonal therapy. These results show that apalutamide made a significant difference in prolonging the time before the development of metastasis,” said lead study author Eric J. Small, MD, FASCO, professor of medicine at the University of California, San Francisco.

Castration-Resistant Prostate Cancer

Many men with prostate cancer recurrence following local treatment with surgery or radiation therapy are treated with hormonal therapy, termed androgen deprivation therapy (ADT). Prostate
cancer that subsequently develops resistance to ADT is termed castration-resistant. There are no FDA approved agents for the treatment of non-metastatic castration resistant prostate cancer (nmCRPC), and some physicians advocate watchful waiting for these patients. However, men whose prostate-specific antigen (PSA) score is rapidly rising while on ADT (with a PSA doubling time of less than 8 to 10 months) are at a significantly increased risk of developing metastases or death. This group represented the men enrolled in the SPARTAN study.

**About the Study**

The SPARTAN Study was conducted at 332 institutions worldwide and enrolled 1,207 men. People with nmCRPC that had stopped responding to ADT and who were at high risk of metastasis based on a PSA doubling time of 10 months or less were randomly assigned to receive apalutamide or placebo taken as daily tablets, added to ongoing ADT. At the time of development of metastases, patients were treated with standard second therapies at their physician’s discretion and had an option to receive on-study abiraterone acetate and prednisone, a standard of care.

**Key Findings**

The median PSA doubling time at study entry was approximately 4.5 months in both the apalutamide and placebo groups. Apalutamide decreased the risk of metastasis and death by 72% compared with placebo and significantly prolonged the median metastasis-free survival by 2 years (40.5 months in the apalutamide group vs 16.2 months in the placebo group). At this interim analysis for overall survival, researchers also noted a trend favoring improved overall survival for men receiving apalutamide versus placebo, although the difference was not statistically significant. Following the analysis of metastasis-free survival, study treatment was unblinded in July 2017 following the recommendations of an Independent Data Monitoring Committee, and all patients were offered open-label apalutamide.

Apalutamide was well tolerated, with 10.7% of men discontinuing treatment due to adverse events, compared with 6.3% of men receiving placebo. Quality of life scores were maintained in those men receiving apalutamide added to ADT.

“These data demonstrate that the use of apalutamide prior to the development of metastases clearly benefited patients whose prostate cancer no longer responded to conventional hormonal therapy,” said Dr. Small. “It is exciting that there now exists such a well-tolerated agent for this group of high-risk patients for whom no approved therapies currently exist.”

**Next Steps**

The authors hope to identify those patients who benefited the most from apalutamide by analyzing
molecular and circulating markers from blood samples. They will also look in greater depth at patient-reported outcomes that evaluate the trial success or failure from a patient perspective.

The SPARTAN study was funded by Aragon Pharmaceuticals, Inc., a wholly-owned subsidiary of Johnson & Johnson.

View the full abstract.

For your readers:

- Guide to Prostate Cancer

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View the disclosures for the News Planning Team.

ATTRIBUTION TO THE 2018 GENITOURINARY CANCERS SYMPOSIUM IS REQUESTED IN ALL NEWS COVERAGE.

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About the American Society for Radiation Oncology:
The American Society for Radiation Oncology (ASTRO) is the world’s largest radiation oncology society, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals who specialize in treating patients with radiation therapies. The Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three peer-reviewed journals, the International Journal of Radiation Oncology • Biology • Physics (redjournal.org), Practical Radiation Oncology (practicalradonc.org) and Advances in Radiation Oncology (advancesradonc.org); developed and maintains an extensive patient website, RT Answers (rtanswers.org); and created the Radiation Oncology Institute (roinstitute.org), a nonprofit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org, sign up to receive our news and follow us on our blog, Facebook and Twitter.

About ASCO:
Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube.

About the Society of Urologic Oncology:
The Society of Urologic Oncology (SUO) was created in 1984 to enable qualified members primarily interested in the care of patients with malignant genitourinary diseases to meet for the purpose of discussion, development, and implementation of ideas to improve care. The Society and its bylaws conform to the guidelines and bylaws of the American Urological Association (AUA).

The purpose of the SUO is to develop educational and research initiatives and to study issues in urologic oncology and provide physician statements that represent a state of the art assessment of these issues to other organizations.

The Society also provides a forum for identifying the urologic oncologist as a physician with specific expertise in the study and treatment of genitourinary malignancies. In recognition of the multidisciplinary efforts involved in the study and treatment of genitourinary malignancies, the Society seeks to incorporate multiple disciplines in achieving these goals. The Society supports the activities of multiple disciplines in the common objectives of seeking an increased understanding and successful treatment of genitourinary malignancies.

The SUO seeks to improve the care of patients with malignant urologic disease and to provide a forum for the discussion of problems relating to malignant urologic disease. Our objectives include: 1) Stimulating research in and the teaching of urologic oncology, 2) Disseminating the principles of urologic oncology to the medical profession at large, 3) Bringing urologists into a Society whose work is entirely, or principally with malignant disease, 4) Being identified as the most qualified organization on matters relating to urologic oncology, and 5) Standardize fellowship training in urologic oncology.

Please visit our website or call (847) 264-5901 for more information on how to become a member.