Phase II Trial Shows Novel, Radiolabeled PSMA-Targeted Treatment Provides High Response Rates in Men With Metastatic Prostate Cancer

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Expert Perspective
“Survival rates are low for patients with prostate cancer that has spread to distant parts of the body, and providing effective treatments for this type of cancer has been an ongoing challenge for physicians. For this group of patients in dire need of new options, using an entirely new approach, this study provides hope that we can start to change their outcomes,” said ASCO Expert Robert Dreicer, MD, MS, MACP, FASCO, moderator of today’s presscast.

ALEXANDRIA, Va. – A single-arm, phase II trial in men with PSMA-positive metastatic, castration-resistant prostate cancer (mCRPC) that progressed despite standard therapies, found that in the majority of men, the cancers were responsive to treatment with a novel, targeted radiation therapy called Lutetium-177 PSMA-617 (LuPSMA). This is the first prospective study of LuPSMA, part of a potential new class of treatments for men with metastatic prostate cancer. According to the researchers, men receiving the medication lived a median of 13.3 months after treatment, longer than the average 9-month survival time for men with this stage of disease. These findings will be presented at the upcoming 2019 Genitourinary Cancers Symposium in San Francisco, California.

“For men with localized prostate cancer, brachytherapy, or radioactive seeds implanted by needle directly into the tumor, as well as external beam radiotherapy, have been effective forms of treatment,” said lead study author Michael Hofman, MBBS, a professor of nuclear medicine at the Peter MacCallum Cancer Centre, Melbourne, Australia. “However, for men in our trial, with cancer
cells spread throughout the body, LuPSMA provides a new approach to a form of the disease that has been difficult to treat."

LuPSMA is composed of a small-molecule targeting ligand that selectively targets prostate-specific membrane antigen (PSMA) – a receptor common on prostate cancer cells – attached to Lutetium-177, a radioactive payload. With this approach, LuPSMA delivers high doses of radiation precisely to the cancer metastases, while avoiding delivery of potentially hazardous radiation to normal cells.

The half-life of the radioactive payload (the time at which radioactivity falls to half of its original value) is seven days. Additionally, LuPSMA emits low levels of gamma rays, which can be visualized with nuclear medicine imaging, which allows clinicians to see if the cancer is regressing.

**About the Study**

All patients enrolled in the trial were diagnosed with a form of mCRPC in which PSMA is present on the surface of the cancer cell, when scanned with positron emission tomography (PET).

Prior to enrollment, the men, ages 50 to 87, saw their PSA levels rapidly double after a median of 2.6 months. Because of the aggressiveness of the disease, most had previously been treated with docetaxel chemotherapy or antiandrogen therapy (abiraterone and/or enzalutamide). Forty-eight percent had also received second-line cabazitaxel chemotherapy.

In this trial, clinicians administered up to four intravenous cycles of LuPSMA in an outpatient setting every 6 weeks and tracked prostate-specific antigen (PSA) levels and imaging using CT, bone or PET scans. In some patients in whom the cancer responded but subsequently progressed, further cycles of LuPSMA were administered.

**Key Findings**

A PSA decline of 50% or more was seen in 32 of the 50 men in the study. In 22 of them, PSA declined 80% or more. Among men in which the cancer responded to LuPSMA therapy, PSA values did not increase for a median of 6.9 months, indicating that the disease was not progressing. Fourteen of the men in whom the cancer progressed received a median of two more cycles of LuPSMA. In nine of these men, PSA subsequently declined 50% or more; survival in this group of men was 33 months.

The most common side effects were nausea, fatigue, and dry mouth as PSMA is also present on cells in salivary and tear glands. Some of the more serious side effects of the drug, seen in about 10% of the men, were anemia and thrombocytopenia, which is a low blood platelet count.

"In this trial, we treated men who would have otherwise been directed to palliative care,” said Dr.
Hofman. “It’s exciting to see that LuPSMA can potentially offer benefits for many men with these very aggressive cancers, with few side effects and significant improvements in quality of life. Importantly, we saw continued benefits with LuPSMA retreatment in some men whose cancer progressed.”

Next Steps

Based on positive early-stage results, two randomized trials have been launched to further evaluate LuPSMA. One trial compares LuPSMA with chemotherapy and the other with the standard of care, according to the study authors.

This study was sponsored by the Peter MacCallum Cancer Centre, Melbourne, Australia. PSMA-617 was supplied by Endocyte (Indiana, USA), and Lutetium-177 by ANSTO (Sydney, Australia).

View the full abstract.

For your readers:

- Guide to Prostate Cancer
- Understanding Radiation Therapy
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View the disclosures for the News Planning Team.

ATTRIBUTION TO THE 2019 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 premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, 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 medical journals, *International Journal of Radiation Oncology, Biology, Physics*
Practical Radiation Oncology, and Advances in Radiation Oncology, developed and maintains an extensive patient website and created the Radiation Oncology Institute, a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. Learn more about ASTRO.

About the American Society of Clinical Oncology:
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 nearly 45,000 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.