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Memorial Sloan Kettering Cancer Center

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In 2019, Michael Rosenblum received an experimental new prostate cancer treatment after the disease spread to his bones. Since then, he has been symptom-free. The treatment is now FDA-approved.

Prostate cancer treatment took a major step forward today as the U.S. Food and Drug Administration approved a new therapy that zeros in on cancer cells to destroy them. The treatment, called ^{177}Lu-PSMA-617, uses a molecule that selectively seeks out and attaches to a specific protein on the cancer cell surface called PSMA (prostate-specific membrane antigen). The technology delivers radiation that damages DNA and destroys the cancer cell.

“This type of precision medicine is a game changer for people whose prostate cancer has spread despite receiving multiple treatments,” says Memorial

Sloan Kettering Cancer Center medical oncologist Michael Morris. He helped design, execute, and analyze a clinical trial showing the effectiveness of ^{177}Lu-PSMA-617. “FDA approval of this therapy will enable even more people who had essentially been given death sentences to survive and live well.”

This treatment, developed by the pharmaceutical company Novartis, could be a breakthrough for treating prostate cancer after it has spread and grown resistant to other drugs. Prostate cancer is the second leading cause of cancer death in American males and kills 34,000 people in the U.S. every year.

The FDA approval is the latest bold advance in the emerging field of theranostics, which uses radioactive substances to visualize cancer cells and destroy them without harming normal cells. It also enables doctors to determine how well a treatment is actually working.

“We have a theranostic motto, which is ‘We see what we treat, and we treat what we see,’ ” says nuclear medicine physician Lisa Bodei, Director of Targeted Radionuclide Therapy at MSK. She is an expert specializing in using radioactive materials to diagnose and treat cancer and played a key role in the treatment of MSK participants in the trial.

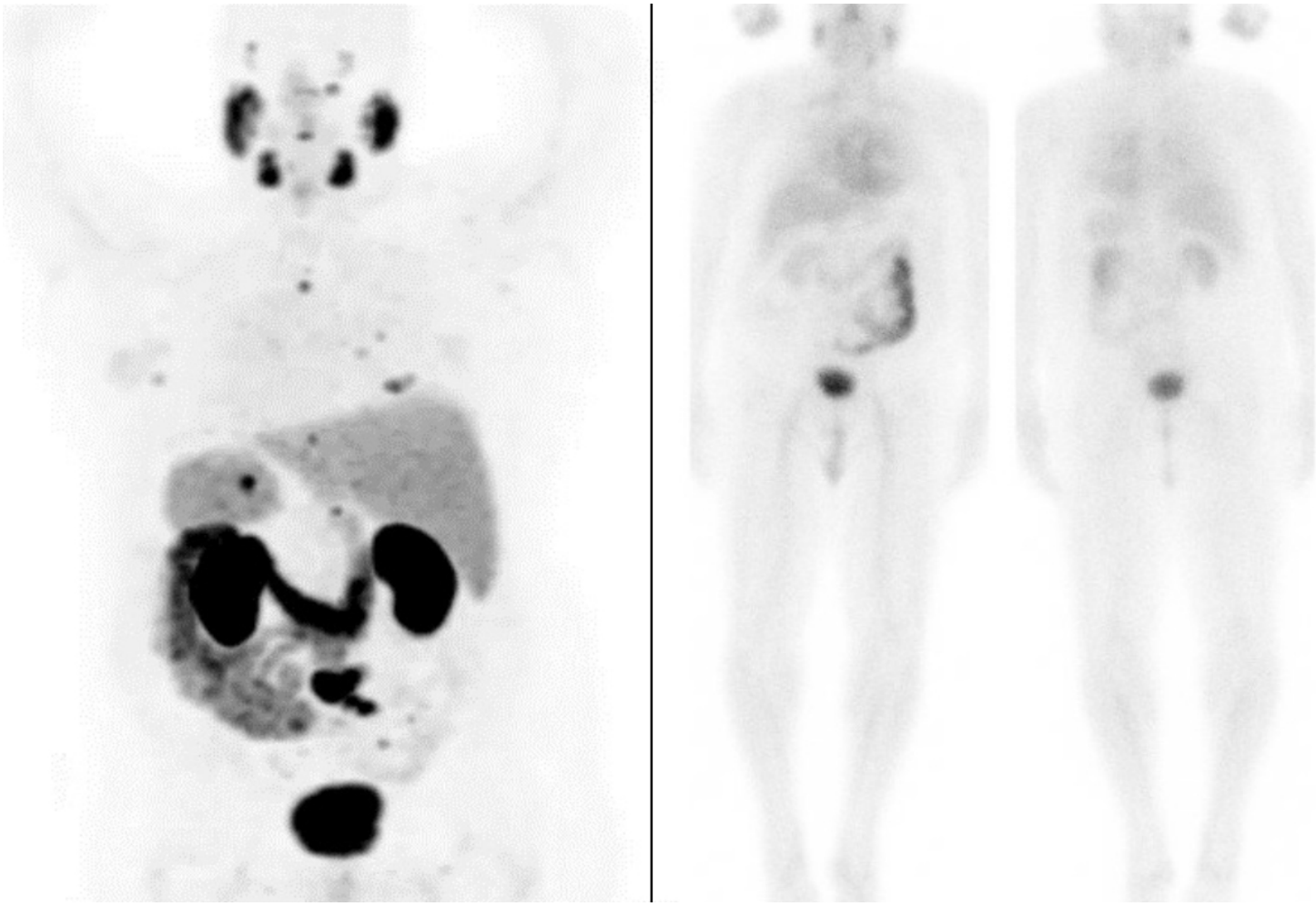
The clinical trial, called VISION, showed that adding the drug to standard treatment slowed progression of prostate cancer. Dr. Morris presented results from this trial in June 2021 at the annual meeting of the American Society of Clinical Oncology. The results also were reported in *The New England Journal of Medicine*.

A New Lifeline

The new therapy could be a lifeline for many people with metastatic prostate cancer. Just ask Michael Rosenblum. In 2019, his prostate cancer was resistant to chemotherapy and other treatments and had spread. PET scans showed dark clusters of cancer cells in bones throughout his body. His PSA levels — a marker that normally should be in the single-digit range — had soared to more than 100.

Dr. Morris enrolled Michael in the VISION clinical trial. Michael began treatment in July 2019 and ended in February 2020. After six doses of the therapy, follow-up scans showed the metastatic cancer was no longer visible. The 76-year-old continues to be disease-free, with a PSA that is undetectable.

“I had no side effects either on the day of the procedures or afterward,” Michael says. “My PSA went right down, and my blood tests have been really good. From how I feel today, you would never think I had cancer a few years ago.”



PSMA-PET scans of Michael Rosenblum before treatment (left) show prostate cancer metastases (small dark spots) throughout his body. After treatment (right), metastatic cancer is no longer visible.

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How PSMA Lights Up Cancer Cells

In 2021, the U.S. Food and Drug Administration issued national approval to two new prostate cancer imaging tests based on similar technology. On a PET scan, the test lights up the cancerous cells that would otherwise be hidden, enabling doctors to precisely target treatment.

Both advances in imaging and therapy rely on targeting PSMA, which is not found on most normal cells but is overexpressed in cancer cells, especially those that have spread. The PSMA molecule was cloned at MSK in the early 1990s.

The Molecular Imaging and Therapy Service, led by Heiko Schöder, played a key role in the development and testing of a slightly different PSMA-directed imaging technology at MSK.

“This advance is the result of years of work by the community of physicians promoting the use of PSMA agents,” Dr. Schöder says. “It’s gratifying to see a collaborative effort result in a breakthrough that has the potential to make a difference for so many patients with advanced prostate cancer.”

Finding Hidden Cancer Cells: FDA Approval of New Imaging Tool Could Transform Treatment Decisions for Advanced Prostate Cancer

A newly approved imaging technology can identify the location of prostate cancer cells, allowing doctors to choose the best treatment.

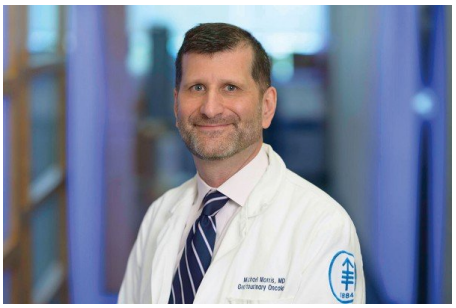
Learn more

Before receiving the therapy, patients in the VISION trial were scanned with PSMA-directed PET imaging to make sure enough PSMA was present in the cells to make them likely to respond to the treatment. If so, they received the radioactive drug by injection over four to six sessions, spaced six weeks apart.

Those who received the new treatment along with standard therapy had a 38% reduction in risk of death compared with those who received standard therapy alone — with a difference in median survival of 15.3 months versus 11.3 months. Also, the length of progression-free survival (the period when the disease didn't get worse) for those receiving the new treatment more than doubled from a median of 3.4 months to a median of 8.7 months. Side effects were more common in people receiving the new treatment but were well tolerated. The most common was dry mouth.

As a next step, Dr. Morris and colleagues are looking into using the PSMA-directed therapy earlier — rather than only after the prostate cancer has spread.

"I have been involved in the PSMA research since the end of my fellowship at MSK in the late 1990s," says Dr. Morris, whose research has been supported by the philanthropy of John and Susan Magnier and Peter and Jean Scannell. "It's amazing to see it all come to fruition this year. The benefits these advances will bring to men with this common disease cannot be overstated."



Michael Morris

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What Lies Ahead: Leading the Way With Alpha Therapies

The coming years will see even more powerful forms of radioactive therapy. The MSK laboratory of radiochemist Jason Lewis and other researchers are investigating the use of alpha particles, which have a much higher energy — hundreds of times more potent — than the photons used in conventional radiation or beta particles. Not only do alpha particles cause more damage when they slam into cancer cells but their path of destruction is more tightly focused, sparing normal cells.

MSK is building one of the nation's first dedicated alpha particle GMP labs at a U.S. academic institution. (GMP means "Good Manufacturing Practices," which are regulated and enforced by the FDA.)

"These radiopharmaceuticals that we are creating translate very well from bench to bedside," says Dr. Lewis, Chief of the Radiochemistry and Imaging Sciences Service and Director of the Radiochemistry and Molecular Imaging Probe Core Facility. "When you see these striking responses to treatment, it brings real hope for the future and our patients."

Advances in radiotheranostics are supported by The Tow Foundation, long-time contributors to MSK's mission.

Key Takeaways

A new FDA-approved drug could be an effective treatment against prostate cancer that has spread.

The treatment uses a molecule that seeks out and attaches to a specific protein on the cancer cell surface called PSMA

The technology delivers radiation that damages DNA and destroys the cancer cell..

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