

New Treatment Eliminates Bladder Cancer in 82% of Patients

Slow drug-release system TAR-200 found highly effective in treating certain patients with bladder cancer whose tumors were previously unresponsive.

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A new drug-releasing system, TAR-200, eliminated tumors in 82% of patients in a Phase 2 [clinical trial](#) for individuals with high-risk non-muscle-invasive bladder cancer whose cancer had previously resisted treatment.

In the majority of cases, the cancer disappeared after only three months of treatment, and almost half the patients were cancer-free a year later.

“Traditionally, these patients have had very limited treatment options. This new therapy is the most effective one reported to date for the most common form of bladder cancer,” said [Sia Daneshmand, MD](#), director of urologic oncology with [Keck Medicine of USC](#) and lead author of a [study](#) detailing the clinical trial results published in the *Journal of Clinical Oncology*. “The findings of the clinical trial are a breakthrough in how certain types of bladder cancer might be treated, leading to improved outcomes and saved lives.”

How the drug delivery system works

TAR-200 is a miniature, pretzel-shaped drug-device duo containing a chemotherapy drug, gemcitabine, which is inserted into the bladder through a catheter. Once inside the bladder, the TAR-200 slowly and consistently releases the gemcitabine into the organ for three weeks per treatment cycle.

Traditionally, gemcitabine has been delivered to the bladder as a liquid solution that only stays in the bladder for a few hours, which had limited effect destroying the cancer, said Daneshmand, who is also a member of the [USC Norris Comprehensive Cancer Center](#).

“The theory behind this study was that the longer the medicine sits inside the bladder, the more deeply it would penetrate the bladder and the more cancer it would destroy,” he said. “And it appears that having the chemotherapy released slowly over weeks rather than in just a few hours is a much more effective approach.”

The patient population in the clinical trial

The clinical trial, known as the SunRISe-1, was conducted at 144 locations globally, including at [Keck Hospital of USC](#). It included 85 patients with high-risk non-muscle-invasive bladder cancer.

Non-muscle-invasive bladder cancer is the most common form of bladder cancer. The disease is considered high risk when, depending on the type and location of the tumors, the cancer carries a higher chance of recurrence and/or spreading to the bladder muscles or other parts of the body.

The standard treatment for this type of bladder cancer is an immunotherapy drug, Bacillus Calmette-Guérin, which may be ineffective in a percentage of patients. All the patients in the clinical trial had been previously treated with this drug, but their cancer had returned.

“The standard treatment plan for these patients was surgery to remove the bladder and surrounding tissue and organs, which has many health risks and may negatively impact patients’ quality of life,” said Daneshmand.

To offer patients a better option, urologic oncologists treated patients with TAR-200 every three weeks for six months, and then four times a year for the next two years. In 70 out of 85 patients, the cancer disappeared and for almost half the patients, was still gone a year later. The treatment was well-tolerated, with minimal side effects.

The study also showed that administering TAR-200 along with another immunotherapy drug (cetrelimab) did not prove as effective as TAR-200 on its own and had more side effects.

While participants in the clinical trial will be followed for another year, the study is closed to new participants.

The future of slow-release cancer drugs

This clinical trial is one of several ongoing ones investigating the effect of TAR-200 and the slow release of cancer-fighting drugs into the bladder to fight cancer.

“We are at an exciting moment in history,” said Daneshmand, who has been researching this novel treatment since 2016. “Our mission is to deliver cancer-fighting medications into the bladder that will offer lasting remission from cancer, and it looks like we are well on our way toward that goal.”

The U.S. Food and Drug Administration has granted TAR-200 a New Drug Application Priority Review, which means the FDA plans to take quicker action on the application than other applications.

The health care corporation Johnson & Johnson manufactures TAR-200.

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