

# FDA approves 'game changer' immunotherapy drug for bladder cancer

June 1 2016, by Jim Stallard

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Craig Brown and his wife, Lynda, sailing on the Hudson River. Mr. Brown's bladder cancer disappeared after he received atezolizumab as part of a clinical trial at MSK. Credit: Memorial Sloan-Kettering Cancer Center

A new immunotherapy drug, atezolizumab, has been approved for

patients with metastatic urothelial carcinoma, a type of bladder cancer. The drug represents the first new treatment for this form of the disease in more than 20 years and is expected to have a major impact on bladder cancer—the fifth most common form of cancer and the fourth most common in men. Its benefit appears to be lasting in some patients.

People with advanced [bladder cancer](#) have not traditionally had effective treatment options. Although chemotherapy can temporarily hold the disease at bay, it often comes roaring back within months.

Now these patients have a new reason for hope. Today, the FDA approved the immunotherapy drug atezolizumab (Tencentriq) for patients with metastatic urothelial carcinoma, the most common form of the disease. The drug's approval stemmed largely from results of a phase II clinical trial led by Memorial Sloan Kettering medical oncologist Jonathan Rosenberg.

The drug represents the first new treatment for this type of bladder cancer in more than 20 years and could have a major impact on the disease, which is the fifth most common form of cancer and the fourth most common in men. The drug is specifically approved for urothelial carcinoma arising in the urinary tract. (The FDA occasionally approves drugs showing great promise in phase II studies, whereas most drugs typically aren't approved until after completing phase III.)

It is also the latest success story in the burgeoning field of immunotherapy, treatments that exploit the power of the immune system to fight cancer.

"We're seeing people get lasting responses with atezolizumab after chemotherapy has stopped working," says Dr. Rosenberg. "That's a game-changer for these patients, and it represents a huge breakthrough."

Results from the trial, which were published in *The Lancet*, showed that atezolizumab shrank tumors in a significant portion of patients. The benefit appeared to be lasting in many people. Among patients in the clinical trial who had anticancer responses, 84 percent were still responding after about one year.

Although the approval is for use in certain bladder cancer patients only—those with metastatic disease who previously have received chemotherapy—Dr. Rosenberg says this approval might later expand to others with the disease.

"These patients have few options and the existing treatments that are available are very toxic—and none of them are known to prolong life," he says.

## **"A Whole New Spin on Your Life"**

For Craig Brown, who participated in the clinical trial, atezolizumab has been nothing short of a miracle. In early 2014, he was diagnosed with stage IV bladder cancer that had spread to his ribs. He began receiving platinum-based chemotherapy (the most common type) once a week for nearly six months, but the treatment proved to have limited benefit and brought severe side effects.

"The chemo made me extremely tired, and it took a while to wear off," he says. "At some points I could barely get out of bed after receiving it. There was some improvement with the cancer, but not complete remission, and as soon as I stopped taking the chemo, it came back almost immediately."

MSK medical oncologist Dean Bajorin enrolled Mr. Brown in the atezolizumab trial in October 2014. Mr. Brown says the change to his health was immediate and dramatic. Not only did the new drug begin

shrinking the cancer immediately, it also has caused no noticeable side effects during the 19 months he has been on it. He is still receiving atezolizumab once every three weeks under the care of Dr. Bajorin.

"It's been tremendous," he says. "I'm a CPA, and I've been able to work from early in the morning to late at night six days a week like I did before the cancer. The doctors tell me I'm in complete remission. It puts a whole new spin on your life to be this fortunate."

## Providing Lasting Potency

Atezolizumab is one of a new group of immunotherapy drugs called checkpoint inhibitors. These drugs take the brakes off the immune system, allowing it to attack the cancer. The braking molecule targeted by atezolizumab is called PD-L1, which is expressed on the surface of some cancer cells and immune cells and prevents the immune system from recognizing that the cancer cells pose a threat. Other checkpoint inhibitors have already been approved for the treatment of several other cancers, including melanoma, lung, and kidney cancers.

Dr. Rosenberg says that the most impressive benefit of atezolizumab may be its lasting effectiveness.

"That is not something we have seen before with bladder cancer," he explains. "There are some patients whose cancer disappeared completely, even after spreading to other sites. You never saw that on a regular basis with chemotherapy-resistant bladder cancer."

He says upcoming [clinical trials](#) will test atezolizumab in additional bladder cancer patients—either alone or in combination with chemotherapy, angiogenesis inhibitors (drugs that choke off tumor blood supply), or other targeted agents. There also is a great deal of interest in seeing whether atezolizumab can be an effective and safe treatment

earlier in the disease process.

Mr. Brown is delighted at the thought of more [patients](#) having atezolizumab as a treatment option. "I'm able to live now with a far better picture of the future," he says. "This approval is a wonderful thing so that other people may also share in the benefits of this drug."

**More information:** Jonathan E Rosenberg et al. Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: a single-arm, multicentre, phase 2 trial, *The Lancet* (2016). [DOI: 10.1016/S0140-6736\(16\)00561-4](#)

Provided by Memorial Sloan-Kettering Cancer Center

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