# FDA Approves First Immunotherapy for Initial Treatment of Stomach Cancer

Opdivo plus chemotherapy led to a significant improvement in overall survival.

April 22, 2021 By Food and Drug Administration (FDA)

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[On April 16], the U.S. Food and Drug Administration approved Opdivo (nivolumab), in combination with certain types of chemotherapy, for the initial treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma. This is the first FDA-approved immunotherapy for the first-line treatment of gastric cancer.

“Today’s approval is the first treatment in more than a decade to show a survival benefit for patients with advanced or metastatic gastric cancer who are being treated for the first time,” said Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research. “The FDA is committed to bringing new safe and effective treatment options like Opdivo to patients with advanced cancer.”

There are approximately 28,000 new diagnoses of gastric cancer each year in the U.S. With currently available therapy, overall survival is generally poor; the rate of cure with resection is very low and the survival rate for all stages is 32%. The 5-year survival rate for advanced or metastatic gastric cancer is 5%.

Opdivo is a monoclonal antibody that inhibits tumor growth by enhancing T-cell function. Its efficacy was evaluated in a randomized, multicenter, open-label trial of 1,581 patients with previously untreated advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma.

The 789 patients who received Opdivo in combination with chemotherapy, on average, lived longer than the 792 patients who received chemotherapy alone. Median survival was 13.8 months for patients who received Opdivo plus chemotherapy compared to 11.6 months for patients who received chemotherapy alone.

The most common side effects of Opdivo in combination with chemotherapy include peripheral neuropathy (damage to the nerves outside of the brain and spinal cord), nausea, fatigue, diarrhea, vomiting, decreased appetite, abdominal pain, constipation and musculoskeletal pain.

Opdivo can cause serious conditions known as immune-mediated side effects, including

inflammation of healthy organs such as the lungs (pneumonitis), colon (colitis), liver (hepatitis), endocrine glands (endocrinopathies) and kidneys (nephritis). Patients should tell their healthcare providers if they have immune system problems, lung or breathing problems, liver problems, have had an organ transplant, or are pregnant or plan to become pregnant before starting treatment.

Opdivo received Priority Review and Orphan Drug designations for this indication. Priority Review designation directs overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

The FDA granted approval to Bristol-Myers Squibb Company.

This review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this review, the FDA collaborated with the Australian Therapeutic Goods Administration, the Brazilian Health Regulatory Agency, Health Canada and Switzerland’s Swissmedic. The application reviews are ongoing at the other regulatory agencies.

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