

Targeted agent shows promise in biliary cancer study

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An experimental agent has shown promising results in people with advanced biliary cancer, according to a multi-institutional clinical trial led by cancer researchers at the Ohio State University.

The agent, known as AZD6244 (ARRY-142886), blocks certain enzymes that [cancer cells](#) need to proliferate and survive.

About 100,000 patients are diagnosed with biliary cancer worldwide every year, representing 15-20 percent of all liver cancer cases. Most patients present at later stages of the disease, which has a universally poor outcome.

The findings of the 28-patient, phase II study will be reported April 20 at the annual meeting of the American Association for Cancer Research in Denver, Colorado.

"This is a malignancy for which there is no standard of care," says the study's principal investigator Dr. Tanios Bekaii-Saab, assistant professor of medicine and pharmacology, and a medical oncologist who specializes in [gastrointestinal cancers](#) at Ohio State's Comprehensive Cancer Center-James Cancer Hospital and Solove Research Institute.

"And while it is a small study, it provides a strong rational for developing this agent further in larger trials either alone or in combination with other drugs, with the hope that we can establish a new standard of care for biliary cancers in the near future."

Bekaii-Saab noted that the average progression-free survival achieved by patients in the study was one of the highest reported in the literature for this malignancy with many patients gaining weight in a disease that is typically associated with significant weight loss. The drug, which is administered orally, seems to be well tolerated with mild toxicities.

The agent belongs to a class of drugs called protein kinase inhibitors. This particular drug targets a protein kinase called MEK 1/2, which is part of a chemical pathway that is often damaged in many biliary cancer cases, Bekaii-Saab says.

In addition to Ohio State, study sites included the University of North Carolina, Vanderbilt University and Emory University.

The patients, with an average age of 56 years, had advanced (metastatic) biliary cancer.

By the trial's end, one patient had a complete response to the treatment (the tumor shrank until it was undetectable), two patients had partial tumor shrinkage and 17 patients showed no further growth in tumor size; that is, they had stable disease which often was durable.

A preliminary analysis of the study shows that patients experienced no cancer progression for 5.4 months on average, a time almost double what would typically be expected with therapy in biliary cancer. This is despite the fact that 40 percent of patients had one prior therapy before receiving AZD6244. A more final analysis of the study is underway.

Patients who lacked a target protein called pERK did not seem to respond to the drug, suggesting that the drug may not work if the protein is missing in the cancer cells. "This is an important finding, as it suggests that we may be able to identify patients who may not respond to the drug in the future," he adds.

Source: Ohio State University Medical Center

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