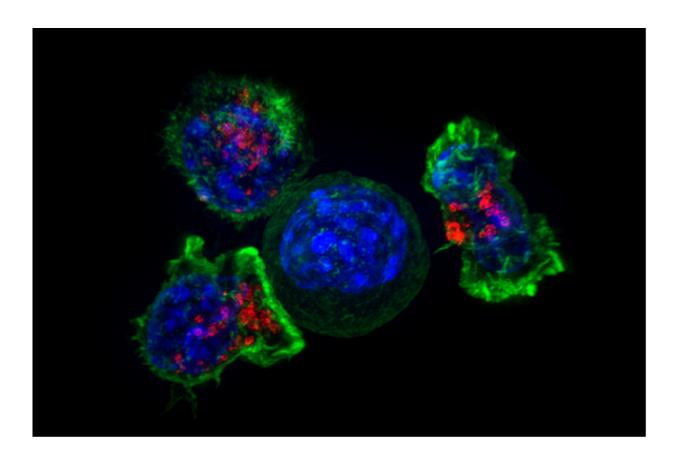


## First-of-its-kind technology lights up lung cancer cells, helps improve patient outcomes

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Killer T cells surround a cancer cell. Credit: NIH

A groundbreaking tumor-highlighting technology—OTL38—enhances the visualization of lung cancer tissue, providing surgeons with a significantly better chance of finding and removing more cancer than



previously possible, according to a scientific presentation at the 56th Annual Meeting of The Society of Thoracic Surgeons.

"Lung cancer is the most common and lethal cancer worldwide," said Inderpal (Netu) S. Sarkaria, MD, from the University of Pittsburgh Medical Center in Pennsylvania. "Technologies to improve the care of these patients are needed. Near-infrared imaging with OTL38 during surgery for lung cancer is one such promising technology with the potential to significantly improve the completeness and quality of the operation, therefore improving <u>patient outcomes</u>."

Dr. Sarkaria and colleagues at six institutions (University of Pittsburgh, University of Pennsylvania, Harvard University, Cleveland Clinic, Leiden University, and MD Anderson) participated in a phase 2 clinical trial, identifying 92 patients who had lung lesions and were to undergo pulmonary resection for non-small cell lung cancer (NSCLC). Before their operations, each patient received a measured intravenous dose of OTL38, composed of near-infrared dye and a targeting molecule. The molecule attaches to folic-acid-based receptors on cancer cells and can be illuminated during surgery using a special surgical endoscope. This helps identify small, hard-to-detect cancer lesions that might otherwise have been missed and should be surgically removed.

The researchers made assessments in three phases: "Lung Inspection," "Tumor Resection," and "Specimen Check." During the inspection phase, the molecular imaging identified 10 additional cancers—all missed when using visual examination and manual touch—in seven patients (8%). In the resection phase, researchers determined that OTL38 enabled localization of lesions that were not found in 11 patients (12%). After surgeons found that all margins were visually adequate or clear in the specimen check, the resected specimens were further assessed using the molecular imaging. Inadequate margins (microscopic residual tumor left at the edges) were uncovered in eight patients (9%).



Overall, researchers determined that the OTL38 molecular imaging helped improve outcomes for 1-in-4 patients (26%).

"OTL38 is the first technique that is specific to imaging adenocarcinomas of the lung, which is one of the most common types of invasive lung cancer, making it unique and clinically useful in this respect," said Dr. Sarkaria. "Localization of tumors, identification of occult tumors, and immediate tumor margin assessment during surgery for adenocarcinomas of the lung were significantly improved with the use of this technology."

Surgery remains the best potentially curative treatment for early stage NSCLC. However, research has shown that 30% to 55% of patients with NSCLC develop recurrence, which often is caused by microscopic clusters of cancer cells that were undetected by standard staging methods. This suggests that complete removal needs to be ensured both macroscopically and microscopically during surgery.

"Near-infrared imaging with OTL38 may be a powerful tool to help surgeons significantly improve the quality of lung cancer surgery by more clearly identifying tumors and allowing the surgeon to better see and completely remove them—one of the most vital components in the overall care of patients with this disease," said Dr. Sarkaria.

Surgeons traditionally use X-rays, magnetic resonance imaging, computed tomography (CT) scans, positron emission tomography, and/or ultrasound to determine the size and location of tumors before surgery. However, these imaging modalities are rarely, if ever, used during surgery.

OTL38 is believed to be the first targeted fluorescent marker to provide this type of benefit for lung cancer. The OTL38 technology is different in its ability to detect cancerous tissue not previously identified on



preoperative scans and do so in real-time, while the surgeon is operating. This is crucial in ensuring that surgeons adequately detect and remove cancer cells that may not be visible to the naked eye or located through touch. The complete removal of diseased tissue during surgery helps to avoid additional surgeries and cancer relapse, as well as increase patients' overall chances of survival.

"Use of advanced near-infrared imaging techniques such as OTL38 may provide surgeons with powerful tools to improve the quality of lung cancer operations by better identifying small, hard-to-find tumors, finding previously undetected cancers at the time of <u>surgery</u>, and better assessing if the entire tumor has been removed," said Dr. Sarkaria.

In addition, with the implementation of <u>lung</u> screening and the increased use of CT scans in general, cardiothoracic surgeons are seeing more patients with small or undefined nodules, so the timing of the availability of technology such as OTL38 is just right, according to Linda W. Martin, MD, MPH, of the University of Virginia in Charlottesville, who was not directly involved with this research.

"In many circumstances, a preoperative biopsy is not practical or feasible, and we are faced with the need for intraoperative identification of these nodules," said Dr. Martin. "This research describes an exciting new approach to localize nodules that are difficult to find without a separate procedure. More importantly, the study showed that because of this technology, additional nodules that were in fact separate cancers were found, and useful information about margin status also resulted."

Dr. Martin described another significant advantage that the OTL38 technology offers—the ability to better identify small nodules. This may allow surgeons to more often utilize minimally invasive operative approaches in some patients who otherwise would have been required to undergo a thoracotomy in order to find these nodules.



The completion of the OTL38 Phase 2 trial in <u>lung cancer</u> is a major milestone, advancing the technology closer to Food and Drug Administration approval and commercialization. Phase 3 trials currently are under way.

## Provided by The Society of Thoracic Surgeons

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