

# OTL38 and Fluorescence-Guided Surgery Fact Sheet

Lung cancer is the leading cause of cancer-related deaths among both men and women in the United States, claiming over 142,000 lives every year—more than colorectal, breast, and prostate cancers combined.<sup>1</sup>

To date there have been limited ways for surgeons to confidently assess the location and full extent of cancerous tissue during surgery. As a result, cancer may remain undetected, impacting patient prognosis and increasing the likelihood of adjuvant treatment.



It is estimated that more than **228,000 people** will be diagnosed with lung cancer in the US this year<sup>2</sup>



**85 to 95 percent** of diagnosed lung cancer is non-small cell lung cancer (NSCLC)



**19 percent** of people diagnosed with lung cancer will survive five years, however, if treated before the cancer spreads, survival rates beyond five years improve dramatically<sup>3</sup>

## Treatment of Non-Small Cell Lung Cancer

Currently, pulmonary resection surgery is the only potentially curative treatment for early-stage NSCLC and, each year, nearly 80,000 patients diagnosed in the U.S. will undergo this procedure. However, approximately **30 to 55 percent of patients who undergo curative resection develop a recurrence and do not survive.**<sup>4</sup>

Overall five-year survival rates for NCSLC patients undergoing a **complete resection improve to 58.5 percent, compared with 33.8 percent for those with an incomplete resection.**<sup>5</sup> Complete resections also reduce the need for a patient to undergo additional operations or adjuvant treatments.<sup>6</sup>

While a complete surgical resection is the most important objective of lung cancer surgery, current methods used to identify malignant tissue are limited. Surgeons rely on a variety of pre-operative scans, additional procedures, and real-time visual and tactile cues, but there is not yet a reliable way to assess the location and full extent of cancerous tissue while operating. **OTL38 has the potential to provide skilled surgeons with the added benefit of intraoperative sight that may increase the likelihood of a more complete surgical resection.**

## How It Works: OTL38 and Fluorescence-Guided Surgery

Fluorescence-guided surgery is an evolving field in which a surgeon's ability to identify malignant tissue in real-time is enhanced by the use of fluorescent imaging agents. OTL38 is one of these agents. It is a fluorescent marker comprised of a near-infrared dye and a targeting molecule (also known as a ligand) that binds to and illuminates cancerous lesions.

Specifically, OTL38 binds to folate receptors that are overexpressed on cancer cells and takes advantage of that overexpression to target and illuminate these cells so they can be identified and removed. The patient receives a single dose of OTL38 via IV infusion one to 24 hours prior to surgery that allows the surgeon to see malignant tissue with the use of a near-infrared camera during the operation.

### FDA Status



FDA Fast Track designation for lung cancer

Phase 3 trial being conducted under Special Protocol Agreement in non-small cell lung cancer



FDA Fast Track designation for ovarian cancer

Orphan designation for ovarian cancer  
Phase 3 trial being conducted under Special Protocol Agreement in ovarian cancer

Currently under development in two Phase 3 clinical trials for ovarian and lung cancer

## About the Multi-Institutional Phase 2 Clinical Trial

To determine if OTL38 improved surgeons' ability to localize hard-to-find lesions, identify additional cancers and discriminate close margins, 92 eligible patients with suspicious lung lesions received 0.025 mg/kg of OTL38 before surgery. Assessments, with specimens verified by two blinded pathologists and stained by immunohistochemistry for folate receptor expression, were made during three phases:



**1. Lung Inspection Phase:**  
Surgeon inspects the chest to localize the primary lesion and identify additional tumors not previously detected



**2. Tumor Resection Phase:** Resection of the cancerous tissue



**3. Specimen Check Phase:**  
Resected specimen is assessed for margin status

### Results



Outcomes improved for **26% of patients** undergoing pulmonary resection for NSCLC



**Ten additional cancers found in seven patients (8%)** using OTL38 and fluorescence-guided surgery



Localization of otherwise unlocalizable lesions in **11 (12%) patients**



Surgeons felt all margins were adequate; however, back-table inspection using fluorescence-guided surgery revealed **inadequate margins in eight patients (9%)**



**No drug-related serious adverse events;** transient infusion-related adverse events, the most common being nausea, were reported in some patients, **all resolving after intervention**

### More Information

The abstract for this study can be found on the STS website for the [STS 2020 Annual Meeting](#). Please follow this path: Monday tab → Plenary Sessions → "J. Maxwell Chamberlain Memorial Paper for General Thoracic Surgery - Multi-Institutional Phase 2 Clinical Trial of Intraoperative Molecular Imaging of Non-Small Cell Lung Cancer" at 9:50 a.m.

### About On Target Laboratories

On Target Laboratories discovers and develops fluorescent markers to target and illuminate cancer during surgery so it can be removed more completely. Their intraoperative molecular imaging technology, based on the pioneering work of Philip S. Low, PhD, reduces the uncertainty associated with finding and removing diseased tissue during medical procedures, empowering surgeons to provide a more precise and complete surgical resection. OTL38, the Company's first compound, is currently under development for use during surgery for ovarian and lung cancer. Additional compounds targeting prostate and colorectal cancer are also in development. For more information visit [www.ontargetlabs.com](http://www.ontargetlabs.com).

### Disclaimer Language

OTL38 is not currently approved by FDA but is an investigational product being researched under an IND in the US and a CTA in EU.

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