

IMAGE GUIDED SURGERY FOR TUMOR AGNOSTIC DETECTION OF SOLID TUMORS USING THE PH ACTIVATED MICELLAR IMAGING AGENT ONM-100

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Background

Fluorescent imaging agents can assist in tumor visualization and margin assessment during surgery. No generic, tumor specific imaging agents have been found yet due to complex oncogenotypes and histologic phenotypes of cancer. Tumor acidosis is a hallmark of cancer due to deregulated tumor metabolism. ONM-100 is designed to exploit tumor acidity and has an exquisitely sensitive binary off/on pH-response. Here, we present the safety and imaging results from the *first-in-human* Phase 1 study in multiple tumor types, demonstrating tumor agnostic imaging feasibility and potential clinical utility of ONM-100.


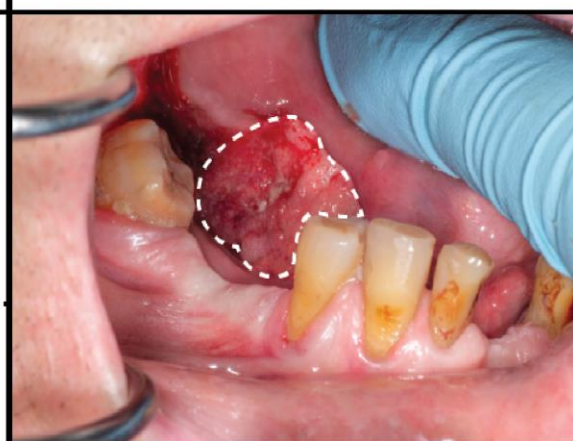
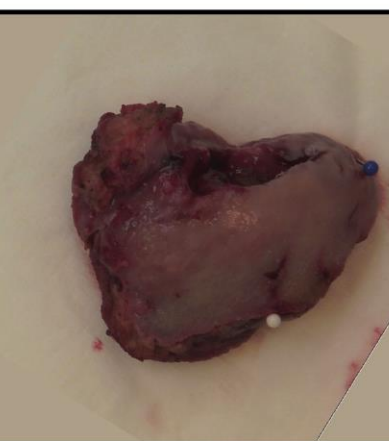
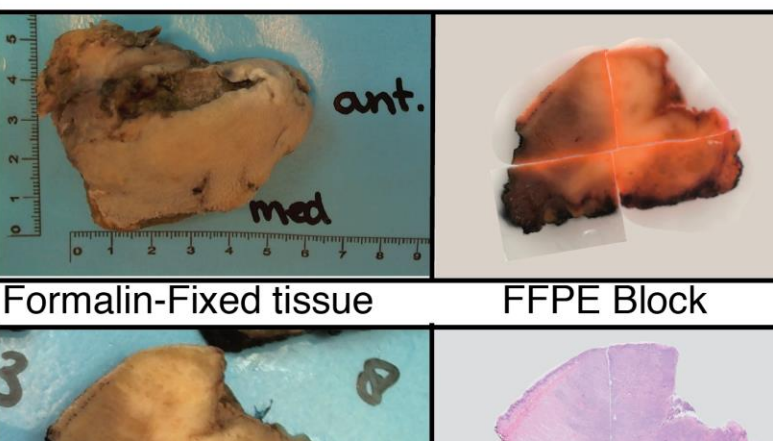


Objective

To evaluate the safety and feasibility of ONM-100 as an intra-operative, near-infrared fluorescent imaging agent in four different solid tumor types.

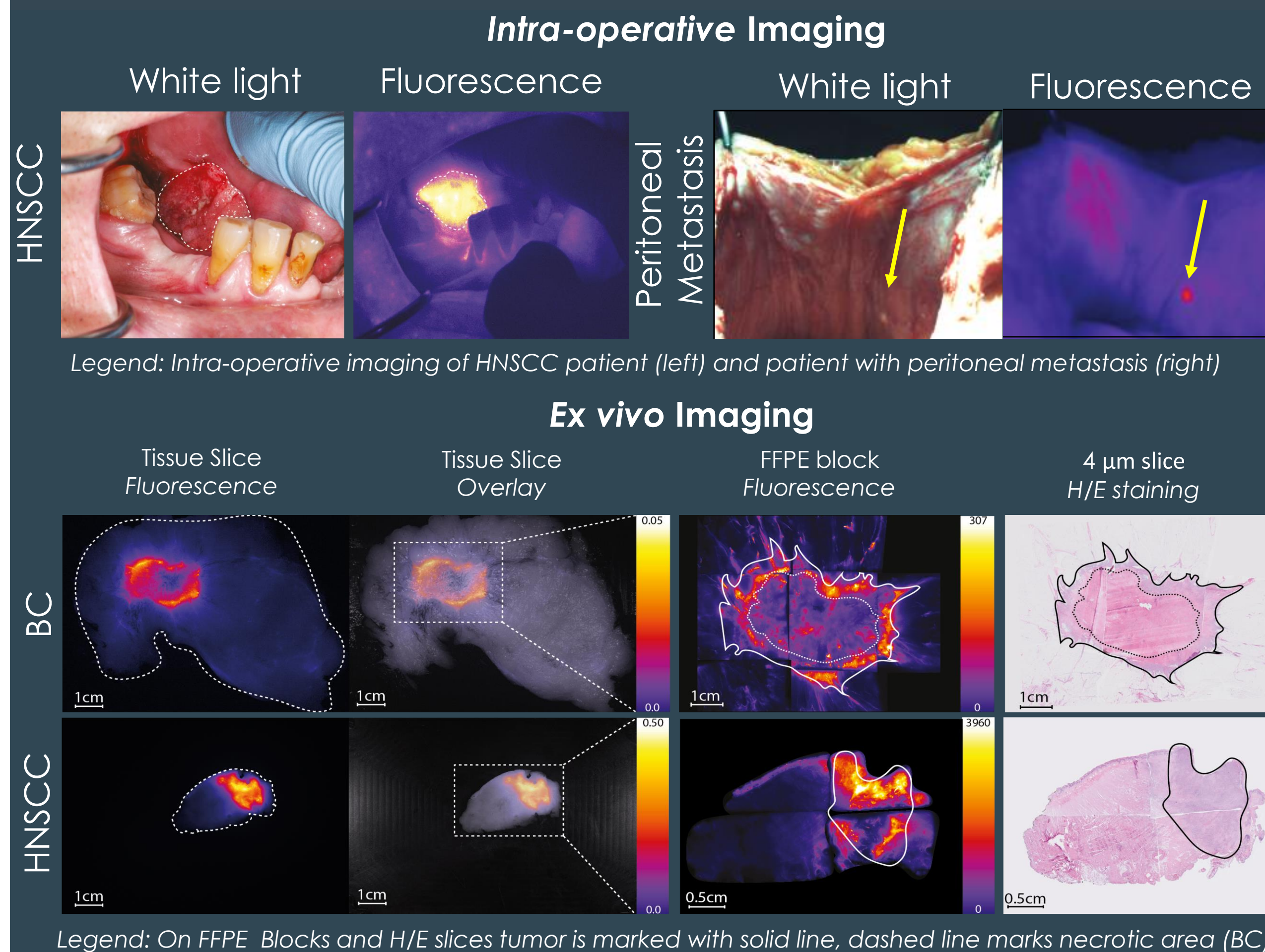
Methods

Patients with solid tumors were enrolled:

- ❖ Histologically proven Head and Neck Squamous Cell Carcinoma (HNSCC), Breast Cancer (BC), Esophageal Cancer (EC) and Colorectal Cancer (CRC)
- ❖ Scheduled for surgical removal according to standard protocol.

ONM-100 administration	Image-guided surgery	Back-table imaging	Histopathological confirmation	Microscopic correlation
 ONM-100 i.v. Safety assessment with ECG, vital signs and physical examination Pharmacokinetic sampling up to day 10 (n=10)	 T= Before and after tumorexcision	 T= Directly after excision	 Formalin-Fixed tissue FFPE Block  Tissue Slices 4 μm H/E slice	 Standard Histology

Imaging Results



In all 29 patients with viable tumor, a strong and sharp demarcated fluorescent signal was visible *in vivo* and *ex vivo* (confirmed by pathology).

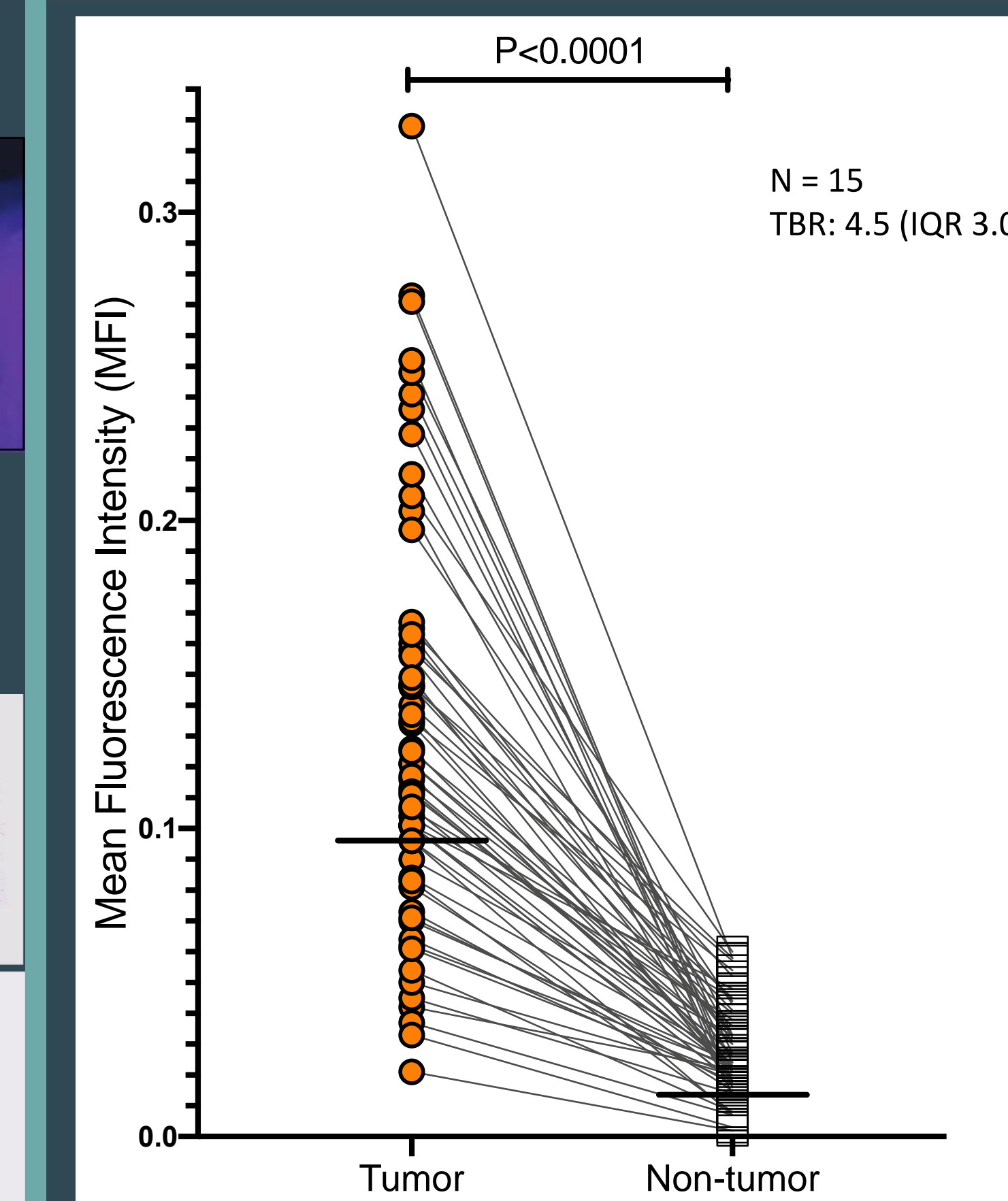
Conclusions & Future Perspectives

This first in human study with ONM-100 shows that this pH-activated imaging agent is well tolerated and provides the first example for generic *in vivo* and *ex vivo* visualization of solid tumors, tumor positive margins and occult disease, demonstrating the potential for significant impact on clinical decision making during surgery.

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Safety and Quantification of Results



Legend: Graph showing Mean Fluorescent Intensity (MFI) for tumor and non-tumor tissue in 15 patients in the 1.2 mg/kg group (N=15, median TBR: 4.5 IQR 3.0)

Safety

No treatment-related adverse event >CTCAE grade 1, serious adverse event, or treatment-related aberrations in ECG, vital signs or laboratory was observed.

Imaging results

- ❖ Quantification of fluorescence signals shows a clear difference between tumor tissue and non-tumor tissue (see Graph).
- ❖ In all BC and HNSCC patients, positive surgical margins were detected using ONM-100 intra-operatively (9/9) (data not shown).
- ❖ In four patients (1 HNSCC, 3 BC), ONM-100 fluorescence detected occult lesions that were missed either by SOC surgery or pathology (data not shown). ONM-100 also detected peritoneal metastasis in 2 CRC patients.

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