

V-1 SGM-101, an anti-CEA labelled fluorochrome for the detection of colorectal cancer; results from phase II and an outline of an upcoming multinational phase III

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Discriminating between malignant and benign tissue remains one of the biggest challenges during colorectal surgery, especially in recurrent cases or patients who received neoadjuvant therapy. SGM-101, a fluorescent anti-CEA monoclonal antibody, is developed as an intraoperative imaging agent for the delineation and detection of malignant tissue.

A phase I/II pilot study with SGM-101 enrolled 26 patients with primary, recurrent or peritoneal metastasized colorectal cancer who underwent surgery with curative intent (9 in the dose-escalation and 17 in the expansion cohort). In the expansion cohort 19 of 43 (44%) malignant lesions were identified with fluorescence imaging which were clinically not suspect. These additional lesions were found in 6 patients (35%) which changed their initial surgical plan.

In an extension of the phase I/II study an additional 35 patients (total of 61) were enrolled. The first results from this extension will be presented at the 2nd JSFGS. Moreover the results showed a promising base for the recently opened, first multinational phase III study on fluorescence guided surgery in colorectal cancer. This study will be used to discuss the current challenges encountered during the clinical translation of tumor targeted agents.