SurgiMab advances SGM-101, a novel fluorescent tumor-specific antibody, into pivotal Phase 3 clinical trial to improve surgical outcomes in colorectal cancer patients

SGM-101 has the potential to be the first tumor-targeted fluorescent probe to be marketed for fluorescence-guided surgery (FGS)

Montpellier, France, 16 July 2019: SurgiMab, a late-stage biotechnology company pioneering a new antibody-based fluorescence-guided approach designed to improve cancer surgery and clinical outcomes for patients, today announces that the first surgical procedure was carried out in a pivotal Phase 3 clinical trial of the Company's lead product, SGM-101, in a patient with colorectal cancer (CRC).

SGM-101 is a tumor-specific antibody conjugated to a dye (fluorophore) that fluoresces under near-infra-red light; it selectively targets a marker on the cancer cell surface known as carcinoembryonic antigen (CEA), which is overexpressed by more than 95% of colorectal cancer cells. SGM-101 is being developed to provide cancer surgeons with a novel intraoperative imaging tool that enables them to visualize tumor tissues overexpressing CEA in real-time during surgery. This allows surgeons to more clearly delineate the margin between tumor tissue and healthy tissue, enabling a more accurate and complete resection of tumor tissue beyond what can currently be achieved with standard procedures. It also prevents removal of healthy tissue and allows for better preservation of functional outcomes.

"Cancer surgery can have a dramatic impact on a patient's prognosis and being able to identify and remove all malignant tissue is critical for the long-term success of their overall treatment and recovery," said **Alexander Vahrmeijer, M.D., Ph.D., Oncologic Surgeon from Leiden University Medical Center (Leiden - The Netherlands), and coordinating investigator of the SGM-101 Phase 3 trial**. "*Fluorescence-guided surgery (FGS) is an exciting new approach that allows the surgeon in real-time to differentiate between tumor tissue and healthy tissue, enabling detection of even small metastatic nodules that are invisible to the eye. With more than 400,000 new cases of CRC diagnosed every year in Europe, new approaches that can facilitate the detection of malignant tissue and potentially improve patient outcomes are greatly needed. We look forward to further evaluating the potential of SGM-101 in this study*."

The randomized Phase 3 trial, designed following discussions with the FDA and other regulators, aims to enroll 300 CRC patients in ten clinical centers in Europe and US, and will assess the clinical benefit of using FGS with SGM-101 as the intraoperative imaging agent to identify cancer lesions during the surgical procedure. Patients will be injected with 10mg of SGM-101 four days prior to the scheduled CRC surgical procedure. Preliminary clinical data of the Phase 3 trial is expected in 2020.

SurgiMab is advancing SGM-101 into pivotal Phase 3 trials based on compelling results from a Phase 2 study (n=75) in which residual and otherwise invisible tumor tissue was detected using SGM-101 during FGS. The Phase 2 study, published in *The Lancet Gastroenterology & Hepatology*[1], has shown

[1] The Lancet Gastroenterology & Hepatology, Vol. 3, No. 3, p181–191
Published: January 17, 2018
Safety and effectiveness of SGM-101, a fluorescent antibody targeting carcinoembryonic antigen, for intraoperative detection of colorectal cancer: a dose-escalation pilot study

that the use of SGM-101 during surgery leads to a modification of surgery in 35% of patients with recurrent or peritoneal metastases of CRC by allowing either more aggressive resection of tumor tissue or by preserving healthy tissue.

Dr Françoise Cailler, SurgiMab's CEO, commented, "*We are excited to initiate our pivotal Phase 3 clinical study with SGM-101. If the trial is successful, SGM-101 could become the first marketed product that combines the specificity of monoclonal antibodies and the sensitivity of fluorescent detection to facilitate the visualization and resection of malignant tissue during cancer surgery.*"

Dr Cailler added*, "Our strategy is to develop and obtain regulatory approval in the US and Europe and ultimately to commercialize SGM-101 together with partners in selected markets. We look forward to reporting preliminary data in 2020.*"

-ENDS-

Contacts:

SurgiMab
Dr Françoise Cailler, CEO
E: fcailler@surgimab.com

Citigate Dewe Rogerson
Sylvie Berrebi, Mark Swallow, David Dible
T: +44 (0) 20 7638 9571
E: SurgiMab@citigatedewerogerson.com

About SurgiMab

SurgiMab is a clinical-stage biotechnology company pioneering a new antibody-based fluorescence-guided approach designed to improve cancer surgery and clinical outcomes for patients.

The Company's lead product SGM-101 comprises a tumor-specific antibody that targets carcinoembryonic antigen (CEA), conjugated to a dye (fluorophore) that fluoresces under near-infra-red (700nm) light. SGM-101 is in a pivotal Phase 3 trial in colorectal cancer (CRC) patients. Safety and effectiveness of SGM-101 have both been demonstrated in Phase 1 and Phase 2 clinical trials in patients undergoing surgery for colorectal cancer. SurgiMab is planning to develop SGM-101 and, pending approval, intends to launch and commercialize this specialty product together with partners in selected markets.

SurgiMab was founded in 2011 and is a privately-owned company headquartered in Montpellier (France).

For more information, please visit www.SurgiMab.com