



GamaMabs Pharma starts a phase 2 study of monoclonal antibody GM102 in patients with advanced or metastatic colorectal cancer

C201 phase 2 will study immuno-enhancer antibody GM102, targeting AMHRII as a single agent and in combination with Trifluridine/Tipiracil (Lonsurf®)

Paris and Toulouse, France, September 17, 2018 – GamaMabs Pharma, a biotechnology company developing optimized therapeutic antibodies targeting the Anti-Müllerian Hormone Receptor II (AMHRII) for the treatment of cancer, today announces that it has dosed the first patient in its Phase 2 clinical trial - of GM102 single agent and in combination with Trifluridine/Tipiracil (Lonsurf®) - in patients with advanced or metastatic colorectal cancer (CRC).

GM102 is a first-in-class glyco-engineered (low-fucose) monoclonal antibody targeting tumor antigen AMHRII. AMHRII is re-expressed in approximately 70% of colorectal cancer patients. GM102 exerts its anti-tumor activity through macrophage and NK cell engagement in the tumor microenvironment, resulting in enhanced tumor phagocytosis and ADCC (Antibody Dependent Cell Cytotoxicity).

This phase 2 study resulted from collaborative research with various European academic research centers and hospitals, which unveiled a wide AMHRII expression in human CRC tumors and a substantial expression of the target on tumor cells at the membrane level. These results were published at the AACR Annual meeting in April 2018.

"The C201 study will investigate the anti-tumor activity of GM102 in this new indication and its potential synergism with Lonsurf® for patients who have progressed on prior therapies. Most CRC tumors express moderate to large macrophage infiltration. GM102 therefore has a potential to enhance macrophage phagocytosis on tumor cells in addition to acting synergistically with Lonsurf®," said Isabelle Tabah-Fisch, M.D., GamaMabs' chief medical officer. "This is a key step in the development of our molecule, which has already shown excellent tolerability in patients with gynecological cancers and first signs of activity in the first patients in the phase 1a/1b C101 study, recently presented at the ASCO 2018 conference."

"We are still in serious need of active drugs for our CRC patients," said Professor B. Melichar, investigator at Olomouc University Hospital, Olomouc, Czech Republic. "AMHRII is yet another unexplored target in CRC. GM102 is the latest generation immunological agent to be tested in colorectal cancers, especially those which do not respond to checkpoint inhibitors. We look forward to evaluating this new agent and I am happy to have the first patient already enrolled in the study."

The European multicenter two-parallel non-randomized cohort C201 Phase 2 study will assess objective response rates, immunological changes in the tumor microenvironment, progression-free and overall survival rates for patients with advanced/metastatic colorectal cancers treated with GM102 single agent and in combination with Lonsurf®. The study will enroll patients who have progressed after at least two lines of prior systemic therapies for metastatic or locally advanced disease and have received all prior available therapies (cohort 1) or are candidates to receive Lonsurf® (cohort 2).

Lonsurf® (trifluridine-tipiracil hydrochloride) is a chemotherapy drug, used to treat metastatic colorectal cancer. Servier commercializes Lonsurf® in Europe and other countries outside of the United States, Canada, Mexico and Asia. Taiho Pharmaceutical has the right to develop and commercialize Lonsurf® in the United States, Canada, Mexico, and Asia.

About GamaMabs Pharma

GamaMabs Pharma, a French immuno-oncology biotechnology company, is a leader in the development of optimized antibodies targeting AMHRII for the treatment of cancer. GamaMabs' first-in-class proprietary therapeutic monoclonal antibodies have the potential for broad applications in cancer. GM102 antibody, which targets the Anti-Müllerian Hormone Receptor II (AMHRII/MISR2), is in phase 1b and phase 2 studies in various solid tumors. The company develops low-fucose EMABling® antibodies (license granted by LFB) with increased tumor cell killing properties through a breakthrough activation of immune cells. GamaMabs also has a licensing agreement with MedImmune (USA) to develop an Antibody Drug Conjugate targeting cancer.

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