GamaMabs Pharma to present updated results at 2019 ASCO Annual Meeting from the First-In-Human clinical study of murlentamab in advanced gynecological cancers

Objective responses, good safety and evidence of stimulation of the immune system observed under murlentamab (GM102) single agent and in combination with chemotherapy

Paris and Toulouse, France, May 22nd, 2019 – GamaMabs Pharma, a biotechnology company developing optimized therapeutic antibodies targeting the Anti-Müllerian Hormone Receptor II (AMHRII) for the treatment of cancer, today announces the upcoming presentation of clinical data from the First-In-Human C101 phase Ia/Ib study of murlentamab (GM102), during the American Society of Clinical Oncology (ASCO) Annual Meeting, on June 1, in Chicago, USA.

In this study, 68 heavily pre-treated patients with advanced or recurrent AMHRII-positive epithelial ovarian (EOC), granulosa cell tumor (GCT), cervical and endometrial cancers, received murlentamab as a single agent (n=59) or in combination with carboplatin and paclitaxel (n=9).

No dose limiting toxicity was reported at all doses and schedules tested, as a single agent and in combination with chemotherapy. One partial response with murlentamab single agent (RECIST 1.1) was observed in a patient with GCT. In combination with chemotherapy, 4 of 9 patients (44%) responded to treatment (1 complete and 3 partial responses). Among patients treated ≥ 6 months, 6 of 9 (67%) GCT patients with murlentamab single agent and 4 of 5 (80%) patients in combination (2 cervical and 2 endometrial cancers) had a longer Progression-Free Survival than under their previous systemic treatment (mean improvement of 3.9 and 2.1 months respectively). Blood samples from 25 patients treated with murlentamab single agent showed an increase in classical monocytes, as well as T cell and neutrophil activation.

"These updated data for these heavily pre-treated patients are really encouraging," said Pr. Alexandra Leary, Gustave Roussy Institute (France), principal investigator of the study. "We are very satisfied, especially regarding the combination with chemotherapy that supports the development of murlentamab in all gynecological cancers. This is crucial for patients with cervical cancers who have so few options. The excellent safety of the drug will allow testing combinations of murlentamab with all standard and experimental treatments."

"Murlentamab seems to rewire the tumor microenvironment and reinitiate the immunological antitumoral cascade from macrophage to cytotoxic T lymphocyte activation. It opens the field to a number of indications and combinations for murlentamab, given the AMHRII re-expression found in many solid tumors," said Dr. Isabelle Tabah-Fisch, Chief Medical Officer at GamaMabs Pharma. "In addition to these gynecological data, the first results of murlentamab in advanced colorectal cancers will be presented at the upcoming 21st ESMO World Congress on GI Cancers."

Murlentamab is a first-in-class glyco-engineered (low-fucose) monoclonal antibody selectively targeting AMHRII-expressing tumors. AMHRII, an embryonic receptor involved in the regression of the Müllerian ducts in the male embryo, is constitutively

expressed in ovarian granulosa cell tumors (GCT) and is re-expressed in a majority of gynecological cancers and a variety of non-gynecological cancers. Murlentamab is currently being evaluated in two clinical trials, phase 1b in gynecological cancers and phase 2 in advanced or metastatic colorectal cancers. Murlentamab exerts its anti-tumor activity through tumor-associated macrophages reprogramming, resulting in enhanced tumor phagocytosis and subsequent cytotoxic T cell reactivation.

Results will be presented at the 2019 ASCO Annual meeting in Chicago, during the Developmental Immunotherapy and Tumor Immunobiology session to be held on Saturday June 1, 8:00 AM-11:00 AM (Hall A) and during the poster discussion session at 1:15 PM - 2:45 PM (Hall D).

Abstract # 2521; 'First-in-human phase I trial of murlentamab, an anti-Mullerian-hormone receptor II (AMHRII) monoclonal antibody acting through tumor-associated macrophage (TAM) engagement, as single agent and in combination with carboplatin (C) and paclitaxel' by A Leary and co-authors.

About GamaMabs Pharma

GamaMabs Pharma, a French immuno-oncology biotechnology company, is the 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. Murlentamab, which targets the Anti-Müllerian Hormone Receptor II (AMHRII/MISR2), is in phase 2 stage of development 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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