GamaMabs Pharma receives Orphan Drug Designation from US FDA for lead compound GM102

This designation has been awarded for the treatment of AMHR2-expressing ovarian cancers, exclusive of AMHR2-expressing fallopian tube cancers and primary peritoneal cancers

Paris and Toulouse, France, February 7, 2018 – GamaMabs Pharma, a biotechnology company developing optimized therapeutic antibodies targeting the Anti-Müllerian Human Receptor II (AMHR2) for the treatment of cancers, today announces that GM102 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA).

GM102 is a first-in-class monoclonal antibody targeting AMHR2-expressing tumors. It exerts its anti-tumor activity through macrophage engagement resulting in tumor phagocytosis. The first-in-human GM102 Phase Ia/Ib trial is ongoing in gynecological cancers, with initial results expected in the first half of this year.

"We are delighted that our lead drug, GM102, has received Orphan Drug Designation from the FDA," said Isabelle Tabah Fisch, Chief Medical Officer of GamaMabs. "GM102 belongs to a new generation of immunotherapies; it brings hope to this subgroup of patients with advanced ovarian cancers. We are committed to the rapid progress of the clinical development of GM102 and look forward to presenting the initial results from our clinical study."

To receive FDA Orphan Drug status, a drug must address a rare disease or a condition that affects fewer than 200,000 people in the United States. Orphan Drug Designation by the FDA grants seven years of market exclusivity in the US and has other benefits such as tax credits, protocol assistance and research grants.

Ovarian cancer is the fifth most frequent cause of cancer death in women, with near to 60,000 deaths every year in Europe and the United States[1]. It is estimated that 175,000 women are affected by AMHR2-expressing ovarian cancers in the US.

[1] SEER website, EUCAN-IARC-WHO

About GamaMabs Pharma

GamaMabs Pharma, a French immuno-oncology biotechnology company, is a leader in the development of optimized antibodies targeting AMHR2 for the treatment of cancer. GamaMabs' first-in-class proprietary therapeutic monoclonal antibodies promise to have a broad commercial potential in cancer treatment. GamaMabs' lead project monoclonal antibody GM102 is currently in the clinic for gynecological cancers. The company develops low-fucose EMABling® antibodies (license granted by LFB) with enhanced tumor cell-killing properties through a novel mechanism for immune cell activation. GamaMabs has a licensing agreement with MedImmune (USA) to develop an Antibody Drug Conjugate targeting cancer.

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