



ARMO BioSciences' Immunotherapy AM0010 Receives Orphan Drug and Fast Track Designations from the U.S. FDA for the Treatment of Pancreatic Cancer

Redwood City, CA, November 14, 2016 --- ARMO BioSciences, Inc., a clinical-stage biotechnology company, announced that the U.S. Food and Drug Administration (FDA) has granted the Company's lead investigational immuno-oncology drug AM0010 (PEGylated Interleukin-10) Orphan Drug designation for the treatment of pancreatic cancer. The Agency also granted Fast Track designation for AM0010 in combination with FOLFOX as a second line therapy in patients with advanced metastatic pancreatic cancer. In an ongoing Phase 1 trial, over 340 patients with advanced solid malignancies have been dosed with AM0010, either as a single agent or in combination with standard-of-care chemotherapy drugs or anti-PD-1 antibodies. ARMO plans to initiate a pivotal Phase 3 trial by the end of 2016, using AM0010 in combination with FOLFOX as a second-line therapy in patients with advanced metastatic pancreatic cancer.

"Orphan Drug and Fast Track designations represent key achievements for ARMO as we execute our plans to advance AM0010 into our first Phase 3 trial," said Peter Van Vlasselaer, Ph.D., President and Chief Executive Officer of ARMO BioSciences. "Pancreatic cancer is difficult to detect at early stages and has the highest mortality rate of all major cancers. New treatment options, including immune-based approaches, are urgently needed for these patients. AM0010 has been shown to specifically engage the immune system to induce comprehensive T-cell activation and objective tumor responses in cancer patients with advanced malignancies. We have completed interactions with the FDA to initiate a potentially registration-enabling clinical development plan for AM0010. Our team is committed to our urgent goal of developing a new treatment for patients with advanced metastatic pancreatic cancer."

About Fast Track Designation

The U.S. FDA's Fast Track is a designation for expedited review to facilitate the development of drugs for the treatment of serious or life-threatening conditions which address an unmet medical need.

About Orphan Drug Designation

The U.S. FDA's Office of Orphan Products Development (OOPD) provides incentives for sponsors to develop products for rare diseases. The Agency's Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan Drug Designation qualifies the sponsor of the drug for

development incentives, including marketing exclusivity in the U.S. for seven years after product approval, tax credits, and exemption from the prescription drug user fee.

About Pancreatic Cancer

According to the American Cancer Society's recent estimates, approximately 53,000 people will be diagnosed and approximately 41,800 people will die from this form of cancer in the United States in 2016. Pancreatic cancer accounts for only three percent of all cancer cases in the United States, but is attributed to approximately seven percent of all cancer deaths.

Cancer of the pancreas usually develops without early symptoms. As a result, more than half of patients are diagnosed at a late stage, when one- and five-year survival is only 15% and 2%, respectively.

About AM0010

AM0010 is a PEGylated form of recombinant human IL-10, which has shown sustained anti-tumor effects and a good safety/tolerability profile in patients from multiple oncology indications. Due to its enhanced half-life, AM0010 has strong immune-stimulating effects that induce the activation, proliferation, and survival of intratumoral, tumor-reactive, cytotoxic CD8⁺ T cells in patients. CD8⁺ T cells mediate the tumor clearing effect of this immuno-oncology agent.

About ARMO BioSciences

Founded in 2012, ARMO BioSciences is a clinical-stage company developing immunotherapies focused on multiple difficult-to-treat oncology indications. The company's lead immunotherapy AM0010, a PEGylated form of recombinant human IL-10, primes the tumor micro-environment for immune-mediated therapies and has demonstrated durable clinical responses in several types of cancer, as both a single agent and in combination with standard-of-care chemotherapy or anti-Programmed Cell Death Protein (anti-PD-1) monoclonal antibodies. ARMO plans to initiate the first of several potentially registration-enabling studies for AM0010 in solid tumors. The company also has a robust pipeline of therapeutic cytokines and an anti-PD-1 checkpoint inhibitor.

For more information, please visit www.armobio.com.

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