News Releases

ARMO BioSciences Announces Positive Outcome of First Interim Analysis in SEQUOIA Phase 3 Pancreatic Cancer Study

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Data Monitoring Committee Recommends Study Proceed Without Modification

REDWOOD CITY, Calif., March 26, 2018 (GLOBE NEWSWIRE) -- ARMO BioSciences, Inc. (Nasdaq:ARMO), a late-stage immuno-oncology company, today announced the completion of the first interim analysis in its Phase 3 SEQUOIA study in patients with pancreatic cancer. The Data Monitoring Committee (DMC) for SEQUOIA, a phase 3 clinical trial studying pegilodecakin (AM0010), plus FOLFOX versus FOLFOX alone in patients with pancreatic ductal adenocarcinoma (PDAC), met on March 25, 2018 to conduct the first interim analysis of the study. Based on the review of this interim analysis, the DMC recommended that the study continue without modification. This first interim analysis was intended to determine if it is safe for the study to proceed based primarily on overall survival as well as pharmacokinetics in the first 60 subjects enrolled in the study that received at least 4 months of therapy.

"Clearing the first interim analysis with feedback from the DMC to continue the SEQUOIA study without modifications is a key corporate milestone for ARMO in 2018," said Joseph Leveque, MD, Chief Medical Officer of ARMO Biosciences. "The DMC's recommendation supports the safety profile we have seen with pegilodecakin when combined with 5-fluorouracyl and platinum based chemotherapy which is the basis for a number of difficult to treat cancers. As such, we believe that pegilodecakin in combination with FOLFOX could provide a safe and efficacious therapeutic option for second-line PDAC patients. The SEQUOIA study continues to enroll well and had 178 patients randomized as of March 15th of this year, which keeps us on track to deliver both the second interim analysis and the final data analysis on this pivotal study in 2020."

SEQUOIA is a Phase 3 randomized pivotal clinical trial in PDAC patients, which compares a combination of pegilodecakin and FOLFOX to FOLFOX alone, as a second-line therapy after tumor progression during or following a gemcitabine-containing regimen. The first patient was enrolled in the study in early 2017 and the company plans to enroll approximately 566 patients in total. The second interim analysis, as well as the final analysis, either of which could provide the basis for a Biologics License Application submission to the Food and Drug Administration (FDA), are both expected to be conducted in 2020. The FDA and European Commission (EC) have granted pegilodecakin Orphan Drug designation for the treatment of pancreatic cancer and the FDA has also granted Fast Track designation for pegilodecakin in combination with FOLFOX as a

FDA has also granted Fast Track designation for pegilodecakin in combination with FOLFOX as a second-line therapy in patients with pancreatic cancer.

About AM0010 Immunotherapy

AM0010 (pegilodecakin) is a long-acting PEGylated form of recombinant human Interleukin-10 (IL-10) which exerts an anti-cancer effect by stimulating the survival, expansion and cytotoxic (killing) potential of CD8+ T cells. An abundance of tumor-infiltrating CD8+ T cells is believed to improve the prognosis and lengthen the survival of cancer patients. AM0010 is currently being investigated in SEQUOIA, a pivotal Phase 3 randomized clinical trial in pancreatic cancer. Results from a Phase 1/1b clinical trial in over 350 cancer patients demonstrated a good safety/tolerability profile for AM0010 and sustained anti-tumor effects across several different cancer types, including pancreatic cancer, renal cell carcinoma, NSCLC and others. The U.S. Food and Drug Administration (FDA) and the European Commission (EC) have granted AM0010 Orphan Drug designation for the treatment of pancreatic cancer. AM0010 has also been granted Fast Track designation by the FDA in combination with FOLFOX as second-line therapy in patients with pancreatic cancer.

About ARMO BioSciences

ARMO BioSciences is a late-stage immuno-oncology company that is developing a pipeline of novel, proprietary product candidates that activate the immune system of cancer patients to recognize and eradicate tumors. The Company's lead product candidate, AM0010 (pegilodecakin, PEGylated Interleukin-10), has demonstrated clinical benefit as a single agent, and in combination with both chemotherapy and checkpoint inhibitor therapy, across several tumor types. The drug is currently being investigated in a Phase 3 randomized pivotal clinical trial in pancreatic cancer patients. AMRO also has a number of other immuno-oncology product candidates in various stages of pre-clinical development including: AM0001, an anti-PD-1 monoclonal antibody; AM0003, an anti-LAG-3 checkpoint inhibitor; AM0015, form of recombinant human Interleukin-15 (IL-15); and AM0012, a form of recombinant human Interleukin-12 (IL-12). For more information, please visit www.armobio.com.

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