News Releases

ARMO BioSciences Enrolls First Patient in the CYPRESS 2 Trial Evaluating AM0010 in Non-Small Cell Lung Cancer

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REDWOOD CITY, Calif., March 29, 2018 (GLOBE NEWSWIRE) -- ARMO BioSciences, Inc. (Nasdaq:ARMO), a late-stage immuno-oncology company, today announced enrollment of its first patient in CYPRESS 2, a randomized Phase 2b trial designed to investigate pegilodecakin (AM0010) in combination with nivolumab as a second-line treatment for patients with metastatic non-small cell lung cancer (NSCLC). The CYPRESS 2 trial will focus on NSCLC patients whose tumors express low (<49-1%) or negative (<1%) levels of PD-L1.

"We are pleased to have dosed the first patient in our CYPRESS development program, which will guide our registrational strategy for pegilodecakin in NSCLC," said Joseph Leveque, MD, Chief Medical Officer of ARMO Biosciences. "In our Phase 1 b trial, pegilodecakin showed very encouraging disease control (DCR), overall response (ORR), progression-free survival (PFS) and overall survival (OS) when combined with pembrolizumab or nivolumab, regardless of the PD-L1 expression, tumor mutational burden (TMB) or disseminated disease in NSCLC patients. We expect that the CYPRESS studies could provide confirmatory translational data to our Phase 1b experience and will allow us to define targeted registrational studies with pegilodecakin in these tough to treat patient populations, which could potentially commence as early as 2019."

Cypress 2 is a randomized study seeking to enroll a total of 100 NSCLC patients that will be randomized on a one-to-one basis between the intervention arm which will receive pegilodecakin in combination with nivolumab (Opdivo®), and the control arm which will receive only nivolumab. To be enrolled in the trial, patients must have a confirmed diagnosis of metastatic NSCLC, must have received only one prior course of therapy which does not contain a checkpoint inhibitor and must be confirmed as having low (<49%) or negative PD-L1 (<1%) expression. The primary endpoint on the study is ORR, and secondary endpoints include PFS and OS among others. In addition to PD-L1 expression, key biomarkers such as TMB and gamma-interferon expression profile (GEP) will be evaluated for each patient. The Company is also in the process of enrolling patients in the CYPRESS 1 study, which will evaluate pegilodecakin in combination with pembrolizumab (Keytruda®) in first-line NSCLC patients whose tumors have high PD-L1 expression (>50%).

"With the first patient dosed in our CYPRESS development program, we have achieved another key milestone for the company in 2018," said Peter Van Vlasselaer, PhD Chief Executive Officer of

key milestone for the company in 2018," said Peter Van Vlasselaer, PhD Chief Executive Officer of ARMO Biosciences. "With more than 10 sites already active and screening patients, and many more coming on-line in the coming weeks, we are ahead of schedule and remain on track to deliver on our plans for the CYPRESS studies to provide robust randomized data on NSCLC patients in the second half of 2018. This data will be critical in guiding our design and accelerating the commencement of registrational studies in NSCLC."

Given the unblinded nature of both CYPRESS studies, the company plans to provide periodic updates on progress in each over the course of 2018, and expects to complete enrollment of both CYPRESS 1 and CYPRESS 2 in the first half of 2019.

Additional information on the details of both our CYPRESS 1 and CYPRESS 2 trials can be viewed on www.clinicaltrials.gov.

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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