

amcure Presents First Clinical Data for Lead Compound AMC303 at ESMO 2018 Congress

Data Presented in Proffered Oral Presentation Demonstrates Favorable Safety Profile of AMC303 Supporting Finalization of Phase 1b Extension Cohort

Eggenstein-Leopoldshafen, Germany – 22 October 2018: amcure, a biopharmaceutical company developing first-in-class cancer therapeutics, presented clinical trial data from its lead oncology drug candidate, AMC303, at the European Society for Medical Oncology (ESMO) Congress in Munich. The data presented on Sunday, 21 October in a proffered oral presentation demonstrated the favorable safety profile of AMC303. The company is currently conducting a Phase 1b expansion cohort and expects to publish updates from the study in 2019.

AMC303 is a cyclic peptide targeting CD44v6, a key cell membrane protein in pathways of several receptor-tyrosine kinases, such as c-MET, VEGFR-2 and RON. This approach provides a potential novel mechanism for the treatment of patients with advanced and solid tumors that have already begun to spread throughout the body. Trial results presented at ESMO 2018 have shown the compound to be well-tolerated in 27 patients with a total of 11 different cancer types, with a favorable PK profile. No related serious adverse events (SAEs) were reported, and most frequently reported related events were infusion related reactions and hypersensitivity (grade 1-2, in 22% of patients), followed by nausea, diarrhea and fatigue.

“AMC303 was well tolerated in a heavily pretreated and diverse cancer patient population. The most related adverse events were transient and manageable. AMC303 has thus the potential of being a safe therapeutic option with a unique and additive mechanism of action,” said Dr. Emiliano Calvo, MD, Lead Investigator of the trial at the Hospital Madrid Norte Sanchinarro and Director at the START Madrid-CIOCC Early Phase Clinical Drug Development program.

“These encouraging data support the continuation of the trial into its second part, targeting patients with a moderate to high expression of the target molecule CD44v6 and selected cancer types with a confirmed squamous cell histology. We look forward to updating the community on the progress of this trial and publish additional data sets as they emerge,” added Klaus Dembowski, CEO of amcure GmbH.

The trial, conducted in Belgium and Spain, is designed to assess the safety, tolerability and pharmacokinetics of multiple and increasing doses of AMC303 as monotherapy in patients with advanced metastatic malignant solid tumors of epithelial origin. In addition, the study includes a comprehensive biomarker program. The study was designed to include a broad variety of tumor types in the first part of the study irrespective of the target expression and a tumor type-specific expansion cohort at the recommended dose for a subsequent Phase 2 study. With the expansion cohort, amcure focuses its patient selection on patients with a moderate to high expression of the target molecule CD44v6 in four specific tumor types of squamous tumors: head and neck squamous cell carcinoma (HNSCC), squamous non-small-cell lung carcinoma (NSCLC), esophageal and cervical tumors.

For more information on the trial please visit <http://www.clinicaltrials.gov/>

About AMC303

amcure's lead compound, AMC303, is being developed as a potential treatment for patients with advanced and metastatic epithelial tumors, e.g. pancreatic cancer, head and neck cancer, gastric cancer, colorectal cancer, breast cancer and lung cancer. AMC303 has a high specificity for inhibiting CD44v6, a co-receptor required for signaling through multiple cellular pathways (c-Met, VEGFR-2, RON) involved in tumor growth, angiogenesis and the development and regression of metastases. AMC303 has demonstrated strong effects in various *in vitro* and *in vivo* assays.

About amcure

amcure GmbH is a spin-off from the Karlsruhe Institute of Technology established in 2012. The company develops peptide-based compounds for the treatment of highly metastatic forms of cancer. amcure's most advanced development candidate, AMC303, has entered clinical development and has demonstrated in *in vivo* animal proof-of-concept studies a high efficacy against different types of epithelial cancers. amcure is supported by a grant from the German Federal Ministry of Education and Research.

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