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amcure Announces First Patient Dosed with AMC303 in Phase Ib Extension Cohort Based on Positive Safety Results

Top-line Results of Dose-Escalation Part to be Presented at ESMO 2018 Congress

Eggenstein-Leopoldshafen, Germany – 6 August, 2018: amcure, a biopharmaceutical company developing first-in-class cancer therapeutics, announced today the dosing of the first patient in the extension cohort of its ongoing phase I/IIb study evaluating AMC303, amcure’s lead compound. The decision to move into the second part of the clinical trial protocol was based on positive safety and pharmacokinetic data obtained in the dose escalation part and a recommendation by the data safety monitoring board. amcure will present top-line data from the dose-escalation part of the trial in an oral presentation at the European Society for Medical Oncology (ESMO) Congress, October 19-23 in Munich/Germany.

AMC303 targets CD44v6, a key cell membrane molecule in pathways of several receptor-tyrosine-kinases, such as c-MET, VEGFR-2 and RON, which are involved in tumor growth and metastases. 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.

The current study, which is being 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. The study also includes a comprehensive biomarker program. With the extension cohort, amcure is focusing 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.

“Our Phase I/IIb study with AMC303 is progressing as planned, demonstrating the safety and linear pharmacokinetic properties in a heavily pre-treated patient population. As drug combinations become increasingly the standard in today’s oncology practice, having a safe therapeutic option with a unique and additive mechanism of action would be an attractive asset. We look forward to continuing the development of AMC303 towards this goal with more preclinical data on the drug’s potential and on CD44v6’s disease biology and first clinical data being presented at the upcoming ESMO congress,” said Klaus Dembowsky, CEO of amcure GmbH.

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 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.

Contact:
amcure GmbH
Dr. Klaus Dembowsky
Hermann-von Helmholtz-Platz 1
76344 Eggenstein-Leopoldshafen
Germany
Phone: +49 (0) 7247 934249-4 or +49 (0) 171 7930077
Fax: +49 (0) 7247 934249-9
E-Mail: info@amcure.com
Internet: https://www.amcure.com/

Media requests:
MacDougall Biomedical Communications
Mario Brkulj or Shai Biran, Ph.D.
Phone: +49 89 2420 9345 or +1 781-235-3060
E-Mail: amcure@macbicom.com