Press Release

amcure Initiates Clinical Study in Patients to Test Novel Approach for Treating Advanced and Metastatic Cancers

Eggenstein-Leopoldshafen – 27 October 2016: amcure, a biopharmaceutical company developing first-in-class cancer therapeutics, today announced the initiation and first patient treated in a Phase I/Ib clinical study of their lead program, AMC303, in cancer patients. AMC303 has been developed to target CD44v6, a key molecule in molecular pathways of several receptor-tyrosine-kinases, such as c-MET, VEGFR-2 and RON which are involved in both 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 study, which will be initially conducted in Belgium and Spain, is designed to assess the safety, tolerability and pharmacokinetics of multiple and increasing doses of AMC303 as a monotherapy in patients with advanced metastatic malignant solid tumors of epithelial origin, for example pancreatic, head and neck, colorectal, gastric and lung cancer, among others. The trial will also seek to determine whether responses to AMC303 correlate with the expression of CD44v6, a cell surface protein that acts as a co-receptor for the activation of several receptor-tyrosine-kinases.

“The initiation of the Phase I/Ib study is an important step in amcure’s mission to provide a therapeutic option for patients suffering from cancer when other standard of care treatments have not been effective,” said Klaus Dembowsky, CEO of amcure GmbH. “We believe AMC303 holds great potential because by targeting one specific co-receptor, three relevant oncological pathways are blocked, thus diminishing the means for tumor growth and metastases in patients. We look forward to seeing the results of this initial trial.”

In a February 2016 publication in the peer-reviewed journal *Gastroenterology*, entitled “Inhibition of Tumor Growth and Metastasis in Pancreatic Cancer Models by interference with CD44v6 Signaling,” by the co-founder of amcure, Alexandra Matzke-Ogi et al., the ability of the early lead compound AM001 was clearly demonstrated to reduce the primary tumor and metastases. The data suggest a central role for CD44v6 signaling in tumor growth, metastatic spreading and maintenance of metastases in distant organs as well as the regression of already established metastases, making it a very promising tool for cancer therapy.

About AMC303

amcure’s lead compound, AMC303, has been 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 also 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 2011. 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* proof-of-concept studies a high efficacy against different types of epithelial

cancers. amcure is sponsored by a grant from the German Federal Ministry of Education and Research.

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