ACTUATE THERAPEUTICS ANNOUNCES INITIATION OF PHASE 2 CLINICAL STUDY IN PANCREATIC CANCER

CHICAGO, IL and FORT WORTH, TX – Actuate Therapeutics, Inc. (Actuate), a clinical stage biopharmaceutical company, today announced enrollment of the first patients with first-line advanced pancreatic cancer in a phase 2 study of 9-ING-41, as a new arm of the ongoing phase 1/2 1801 trial of 9-ING-41, (NCT03678883, EudraCT#:2018-003739-32). 9-ING-41 is Actuate's proprietary small molecule glycogen synthase kinase-3 beta (GSK-3β) inhibitor which is being developed for adults and children with advanced refractory cancers.

The pancreatic phase 2 1801 study arm is open-label and designed to evaluate the efficacy of 9-ING-41 in combination with gemcitabine/nab-paclitaxel as treatment of patients with advanced pancreatic cancer in the first-line setting. The study will enroll up to 60 evaluable US and EU patients in a Simon two-stage design, with the primary objective of assessing the disease control rate of the 9-ING-41-based combination regimen.

Actuate is also recruiting patients for their 1901 international phase 2 study of 9-ING-41 as a single agent and in combination with Ruxolitinib in patients with advanced refractory myelofibrosis, (NCT04218071), already open in the U.S. and opening in the U.K.

"The data we presented on the 1801 study at this year's ASCO annual meeting, showing prolonged disease stability in patients with metastatic pancreatic cancer who were refractory to several prior lines of chemotherapy, continue to impress" said Dr. Benedito Carneiro, MD, Principle Investigator on the 1801 study at Brown University, Lifespan Cancer Institute, and presenter of the ASCO 1801 oral abstract (https://meetinglibrary.asco.org/record/185088/abstract.) "We have very positive safety data on 9-ING-41 in a cohort of over 200 heavily pre-treated patients on the 1801 study with objective responses being observed with both single agent 9-ING-41 and when it is combined with standard cytotoxic regimens including with gemcitabine/nab-paclitaxel. We are thus particularly excited to have this study open for our patients as we are to have both the myelofibrosis and pediatric studies of 9-ING-41."

"Pancreatic cancer continues to be one of the deadliest cancers, with less than 10% survival in the US at 5 years. New therapies are desperately needed for this patient population" said Dr. Anwaar Saeed, MD, Principle Investigator on the 1801 study at the University of Kansas, Kansas City. "The pre-clinical data on 9-ING-41 in pancreatic cancer is compelling with evidence of multiple modes of action. The pre-clinical evidence of 9-ING-41's potent anti-fibrotic activity is also intriguing not alone in the context of pancreatic cancer but also in the sarcomas, where 9-ING-41 has significant pre-clinical activity in a broad spectrum of models of both adult and

pediatric disease. We are looking forward to evaluating the combination of this novel safe targeted agent with standard regimens in patients with advanced pancreatic cancer on both the 1801 phase 2 study and potentially with other cytotoxic regimens, including FOLFIRINOX as frontline therapy."

"We are delighted to move the first clinically relevant GSK-3B inhibitor into phase 2 studies in both myelofibrosis and pancreatic cancer" said Ludimila Cavalcante, MD, Medical Director at Actuate Therapeutics. "In parallel with our clinical program, our collaborations focused on pre-clinical work in pancreatic cancer models with colleagues including Dr. Daniel Billadeau at the Mayo Clinic and Dr. Holly Brunton at the University of Glasgow are also expanding. In addition to 9-ING-41's direct anti-neoplastic and anti-fibrotic activities, we are examining its potential to synergize with immune-modulatory approaches, with an initial focus on melanoma and neuroblastoma. I am particularly excited about the caliber and range of investigator-initiated studies being developed by our clinical colleagues with whom we are indeed fortunate to collaborate."

"The opening of this phase 2 study evaluating 9-ING-41 as a potential key component of first line therapy in advanced pancreatic cancer represents another major milestone for Actuate." said Daniel Schmitt, President & CEO. "Based on the compelling preclinical data developed by leading researchers on the effect of GSK-3β inhibition in cancer and fibrotic diseases, and the clinical profile demonstrated by 9-ING-41 to date, we are hopeful that employing 9-ING-41 in first line treatment of pancreatic cancer will bring additional clinical benefit to patients and offer a new therapeutic option in treating this challenging and devastating disease."

About Actuate Therapeutics, Inc.
Actuate is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics for cancers and inflammatory diseases. For additional information, please visit the Company's website at http://www.actuatetherapeutics.com