ACTUATE THERAPEUTICS ANNOUNCES PRIMARY ENDPOINT MET IN PHASE 2 STUDY IN PANCREATIC CANCER

Elraglusib Results in 57% Disease Control Rate and 39% Objective Response Rate in Combination with Gemcitabine/Abraxane in First Line Treatment of Pancreatic Cancer

CHICAGO, IL and FORT WORTH, TX – Actuate Therapeutics, Inc. (Actuate), a clinical stage biopharmaceutical company, today announced that their Phase 2 open-label single arm study of elraglusib (9-ING-41) plus gemcitabine/nab-paclitaxel treatment met its primary endpoint for clinical response in patients with advanced pancreatic cancer in the first-line setting. Thirteen of the initial twenty-three sequentially enrolled evaluable patients in that study demonstrated positive responses to the combination therapy, including two patients with confirmed complete responses (CRs), seven with confirmed partial responses (PRs), and four patients with stable disease of 4 or more cycles, for a disease control rate of 57 percent, which exceeded the prespecified statistical threshold for clinical success in the study.

This trial is the Part 3 expansion arm of the 1801 trial evaluating elraglusib, a novel, small molecule inhibitor of glycogen synthase kinase-3 beta (GSK-3β), in adult and pediatric patients with advanced cancer (NCT03678883, EudraCT#:2018-003739-32).

Expanding upon the successful single arm trial, the company also announced initiation of an international phase 2 randomized controlled trial of elraglusib in combination with gemcitabine/nab-paclitaxel for first line treatment of patients with advanced pancreatic cancer.

“Based on the very encouraging responses seen in the single arm study, we are very pleased to have enrolled the first patients on the randomized controlled clinical study that Actuate consequently and immediately opened. This randomized Phase 2 clinical trial is designed to evaluate first-line treatment with elraglusib when dosed once weekly versus twice weekly in combination with gemcitabine/nab-paclitaxel, versus gemcitabine/nab-paclitaxel alone” said Dr. Benedito Carneiro, Brown University’s principal investigator on the 1801 study. “This study will help define the dosing regimen for elraglusib to take forward in registration studies for first line treatment of pancreatic cancer, a notoriously difficult to treat disease. We are also excited to open our investigator-initiated study of elraglusib in patients with refractory soft tissue sarcomas.”

“We initially focused on elraglusib as a promising therapy for patients with pancreatic cancer based on pre-clinical data of its single agent activity and synergy with gemcitabine”, said Dr. Anwaar Saeed, principal investigator on the 1801 study at the University of Kansas Cancer Center. “As the clinical data on elraglusib has evolved, so has appreciation of GSK-3β inhibition as an immunomodulatory approach in cancer therapy. I am thus very excited to open our investigator-initiated study of elraglusib, gemcitabine/nab-paclitaxel and an anti-PD-1

checkpoint inhibitor in patients with metastatic pancreatic cancer in which we hope to mirror the pre-clinical data on elraglusib's stimulation of NK and T cell effector function and its synergy with checkpoint inhibitors."

"We have observed significant durable responses and a favorable safety profile in patients on elraglusib studies. We are looking forward to enrolling on the randomized study for patients with metastatic pancreatic cancer" said Dr. Devalingam Mahalingam, principal investigator on the 1801 study at Northwestern University. "In addition to its anti-neoplastic and immunomodulatory activity, elraglusib has very potent anti-fibrotic activity in a range of standard pre-clinical models. This may be an important mode of action in a spectrum of adult and pediatric cancers. With my focus on improving the prognosis of patients with GI malignancies, I am particularly interested in conducting an investigator-initiated study in advanced hepatocellular cancer where elraglusib's modes of action may be of benefit."

"Our investigators' satisfaction with the number and durability of responses that patients with advanced pancreatic cancer experienced in the single arm study encouraged us to very rapidly advance to an international randomized controlled study" said Daniel Schmitt, Actuate's President & CEO. "Enrollment of patients in the Phase 2 randomized study represents a major advance in the elraglusib program. With the FDA's recent granting of Fast Track Status for elraglusib for treatment of pancreatic cancer, there is a clear and potentially accelerated path to follow for registration."

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. In addition to this randomized controlled study, Actuate is executing Phase 2 clinical trial for the treatment of myelofibrosis, a Phase 1/2 trial for neuroblastoma in pediatric patients, and a Phase 2 trial in salivary gland carcinomas. The company is also planning additional clinical studies of elraglusib in other cancers including studies for front line treatment of advanced pancreatic cancer both in combination with FOLFIRINOX, and with a checkpoint inhibitor containing regimen. For additional information, please visit the Company's website at http://www.actuatetherapeutics.com