ACTUATE THERAPEUTICS ANNOUNCES FDA FAST TRACK DESIGNATION FOR 9-ING-41 FOR TREATMENT OF PANCREATIC CANCER

CHICAGO, IL and FORT WORTH, TX – Actuate Therapeutics, Inc. (Actuate), a clinical stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for 9-ING-41 for treatment of patients with pancreatic cancer. 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.

"We are pleased with the FDA's decision to grant Fast Track Designation to 9-ING-41 for the treatment of pancreatic cancer. Pancreatic cancer remains an area of high unmet medical need, with less than 10% survival in the US at 5 years. The Fast Track Designation, along with the initiation of our new randomized controlled Phase 2 study protocol for frontline treatment of metastatic pancreatic cancer, further our ability to advance development and regulatory interactions with the FDA to bring 9-ING-41 to patients with this highly lethal malignancy", said Daniel Schmitt, President & CEO.

The FDA's Fast Track program is designed to facilitate the expedited development of drugs to treat serious conditions and unmet medical needs. The Fast Track Designation will allow Actuate to have more frequent FDA interactions related to the 9-ING-41 drug development program as well as rolling review, and potentially priority review, of the company's NDA marketing application.

Actuate first enrolled patients with advanced pancreatic cancer on a phase 2 study of 9-ING-41 combined with gemcitabine/nab-paclitaxel, as an additional arm of the ongoing phase 1/2 1801 trial of 9-ING-41, (NCT03678883, EudraCT#:2018-003739-32).

"Based on the initial data from our ongoing single arm study, we have initiated a randomized Phase 2 study for frontline treatment of patients with metastatic pancreatic cancer" said Dr. Francis Giles, Actuate's Chief Medical Officer. "Patients will be randomized to 9-ING-41 in combination with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel alone. We are also working with lead investigators to launch additional clinical studies of 9-ING-41 for front line treatment of pancreatic cancer in combination with a checkpoint inhibitor and with the FOLFIRINOX 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), and for study 1902 international Phase 1 study as a single agent

or with irinotecan, irinotecan plus temozolomide, or with cyclophosphamide plus topotecan in pediatric patients with refractory malignancies, (NCT04239092).

In addition, investigators at the Dana Farber Cancer Institute are initiating a clinical study of 9-ING-41 in combination with carboplatin in patients with incurable, recurrent or metastatic salivary gland carcinomas and investigators at Brown University are developing a clinical study of 9-ING-41 in combination with gemcitabine and docetaxel in patients with refractory sarcomas. An extension arm of the 1801 trial will examine the activity of 9-ING-41 in patients with refractory Adult T-cell Leukemia/Lymphoma.

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