



ACTUATE THERAPEUTICS OPENS PHASE 1 / 2 CLINICAL STUDY OF 9-ING-41 IN PATIENTS WITH REFRACTORY CANCERS

CHICAGO, IL and FORT WORTH, TX – Actuate Therapeutics, Inc., a clinical stage biopharmaceutical company, today announced the enrollment of the first patients in its 1801 Phase 1 / 2 study of 9-ING-41, a proprietary glycogen synthase kinase-3 beta (GSK-3 β) inhibitor, in patients with refractory hematologic malignancies or solid tumors.

“Opening enrollment on our first multicenter international study of 9-ING-41 is another significant milestone for Actuate and we are delighted to advance our program into the clinic. Under the leadership of Dr. Francis Giles, Actuate Chief Medical Officer, we have been able to design and initiate a cutting edge protocol in a network of global leading trial sites. We look forward to advancing this important program for patients, and expanding both our adult and pediatric clinical programs” said Daniel Schmitt, President & CEO of Actuate.

“We are very excited to have enrolled our first patient in the global 1801 study of 9-ING-41”, said Benedito Carneiro, MD, Director of Clinical Research, Director of Cancer Drug Development, and Associate Director, Division of Hematology/Oncology at the Lifespan Cancer Institute, Providence, RI. “9-ING-41 is the first clinically relevant modulator of GSK-3 β that we have been able to offer our patients. The very extensive preclinical data on 9-ING-41 show both single-agent activity and significant synergy with an array of standard cytotoxic chemotherapy agents in a broad range of solid tumors and lymphomas. As a small molecule specific GSK-3 β inhibitor, 9-ING-41 allows us to modulate a target that has been of major interest in oncology for decades. The development of truly novel first-in-class agents such as 9-ING-41 is our highest priority in our clinical research programs. The 1801 study is designed to move as safely and efficiently as possible through clinical investigation of 9-ING-41 as a single agent and within combination regimens. That will then allow us to rapidly focus on regimens in specific cancer histologies or molecularly-defined patient cohorts that would potentially warrant regulatory approval”.

The 1801 clinical trial will be initiated in over 20 world-leading oncology research institutions in the EU and US.

“The opening of the 1801 study, which marks the advance of 9-ING-41 into the clinic, is particularly exciting” said Razelle Kurzrock, MD, Chair of Actuate’s Scientific Advisory Board and Chief, Division of Hematology & Oncology, University of California San Diego (UCSD) School of Medicine and Senior Deputy Director, Director, Center for Personalized Cancer Therapy at the Moores Cancer Center, UCSD and UC San Diego Health. “9-ING-41 is directed against a potentially very important target that previously has been difficult to modulate. The extensive pre-clinical data indicate that inhibition of GSK-3 β may reverse resistance and enhance response to a spectrum of currently available standard cytotoxic therapies in patients with advanced cancers. The 1801 clinical study is being conducted by very dedicated and

experienced colleagues and I am very eager to see the results we generate and how best to optimize the potential benefit of 9-ING-41 in adults and children”

“We are excited to be able to offer patients a promising truly novel agent that modulates a target that has been of interest for many years” said Pamela Munster, MD, Professor, Department of Medicine (Hematology/Oncology) UCSF, Director, Early Phase Clinical Trials Unit, Co-Leader of the Center for BRCA Research and Leader, Experimental Therapeutics Program, UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco. “GSK-3 is ubiquitously expressed and controls multiple essential signaling pathways in cancer. The targeting of this pathway with promising small molecule inhibitors of GSK-3 β , the isoform considered of most importance in cancer, will provide an entirely novel approach in interfering with tumor growth and progression. The entry of 9-ING-41 into the clinic within the 1801 study is an important step in our ability to assess the relevance of GSK-3 β as a target. The 1801 trial will allow us to investigate both 9-ING-41’s tolerability and efficacy as a single agent and as a modifier of cancer cell resistance in combination with other anticancer agents which will be studied in this international collaboration”

About Actuate Therapeutics, Inc.

Actuate is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutic agents for patients with cancer or inflammatory diseases. For additional information, please visit the Company’s website at <http://www.actuatetherapeutics.com>