# ACTUATE THERAPEUTICS SUBMITS IND APPLICATION FOR TREATMENT OF REFRACTORY CANCERS

CHICAGO, IL and FORT WORTH, TX, January 15, 2018 – Actuate Therapeutics, Inc., a clinical stage biopharmaceutical company, today announced that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) to begin clinical study of 9-ING-41, Actuate's lead agent – a proprietary GSK-3β inhibitor.

This initial IND application supports the initiation of Actuate's first-in human clinical trial, a phase 1/2 study of 9-ING-41 in patients with refractory hematologic malignancies or solid tumors. The clinical trial will be initiated in over 20 world-leading oncology research institutions in the EU and US after successful regulatory reviews of the application.

"The submission of this IND for 9-ING-41 is another significant milestone for Actuate because it will allow us to advance our program into the clinic and make 9-ING-41 available to physicians and their patients as soon as possible" said Daniel Schmitt, President & CEO of Actuate.

The IND application includes two Fast Track designation applications for Glioblastoma and Neuroblastoma. Actuate has already received from the FDA Orphan Drug Designations for these two indications, as well as a Rare Pediatric Disease Designation for Neuroblastoma.

"The preclinical data on 9-ING-41, showing efficacy across a broad range of solid tumors and lymphomas, coupled with an impressive tolerance and pharmacokinetic profile, is quite compelling" said Frank Giles, MD, Chief Medical Officer of Actuate. "GSK-3β is a potentially very important therapeutic target in an array of serious human diseases, including cancer where it has a key role in the development of tumor resistance to current anti-cancer approaches. As a small molecule specific GSK-3β inhibitor, 9-ING-41 could become an integral part of treatment regimens in different tumor types, including in some of the most aggressive cancers in adults and children".

"Advancing promising novel agents, like 9-ING-41, into the clinic is critical for improving the treatment of patients, for many of whom currently there are not effective therapies or alternative approaches" 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 represents a new class of agents directed against an important target that previously has been difficult to modulate. Inhibition of GSK-3β could potentially reverse resistance and enhance response to currently available therapies in patients. The submission of this IND is a key step towards the conduct of the international 9-ING-41 1801 clinical study that has been designed, and will be conducted, by global leaders in oncology clinical research. I am excited to be part of this highly innovative

program, and particularly proud of its immediate focus on both adults and children with very challenging cancers."

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