ACTUATE THERAPEUTICS ANNOUNCES INITIATION OF ADDITIONAL CLINICAL STUDIES FOR 9-ING-41

CHICAGO, IL and FORT WORTH, TX – Actuate Therapeutics, Inc. (Actuate), a clinical stage biopharmaceutical company, today announced the initiation of two additional clinical studies with its lead molecule, 9-ING-41, a Glycogen Synthase Kinase beta (GSK-3β) inhibitor.

On April 8, the company opened its 1902 study*: A Phase 1 study of 9-ING-41, a Glycogen Synthase Kinase 3 Beta (GSK 3β) inhibitor, as a single agent or with Irinotecan in pediatric patients with refractory malignancies***.** Study 1902 will serve as the required Phase 1 safety study prior to initiating Phase 2 studies for treatment of pediatric patients including those with Neuroblastoma, for which the company has received both Orphan Drug and Rare Pediatric Disease Designations from the FDA.

"GSK-3β is well established as a potentially important therapeutic target in patients with neuroblastoma, a malignancy in which there is an urgent need for novel approaches, said Ludimila Cavalcante, MD, Lead Medical Affairs at Actuate. "Multiple investigators have confirmed the activity of 9-ING-41 in pre-clinical models of MYC-N amplified and non-amplified disease, both as a single agent and when combined with cytotoxic therapies. The 1902 study will provide the cornerstone pediatric safety data needed to conduct tumor-specific Phase 2 studies. Aside from direct anti-tumor activity against neuroblastoma, GSK-3β inhibition of PD1 and LAG-3 expression may be reversed by 9-ING-41, which is potentially important in relatively nonimmunogenic cancers, including neuroblastoma."

The company has also recently opened its 1901 study: *A Phase 2 study of 9-ING-41, a Glycogen Synthase Kinase 3 Beta (GSK 3β) inhibitor, as a single agent or combined with Ruxolitinib, in patients with myelofibrosis.*

"9-ING-41 may help to address the major unmet medical need for new treatment options for patients with myelofibrosis", said Frank Giles, MD, Chief Medical Officer of Actuate. "Achieving sustained adequate exposure to JAK inhibitors is necessary for optimal therapeutic outcomes but adverse events, particularly myelosuppression, lead to frustrating and damaging dose reductions or interruptions in many patients. 9-ING-41 has clinical anti-neoplastic activity, significant pre-clinical anti-fibrotic activity, causes no myelosuppression, and is synergistic pre-clinically with Ruxolitinib. It is very exciting to have a unique investigational option to offer patients with an agent that is likely to be synergistic with other novel therapeutic approaches being developed for myelofibrosis."

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"We are particularly fortunate to be able to advance multiple clinical programs in such a challenging environment. With 9-ING-41's favorable safety profile, including the lack of immunosuppression or myelosuppression in patients with diverse advanced malignancies, our clinical collaborators are committed to accrual on both current and new studies". said Daniel Schmitt, President & CEO. "We are able to maintain the momentum of our programs during these very adverse conditions and are very grateful to work with superb clinical and pre-clinical colleagues whose unwavering focus is on improving the prognosis for patients, both adults and children, with cancer."

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

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