NEWS RELEASE

# Actuate Receives FDA Orphan Drug Designation for Elraglusib for Treatment of Soft Tissue Sarcomas

2024-09-11

- Elraglusib is a Class-Leading GSK-3β Inhibitor with a Novel, Multimodal Mechanism of Action in Multiple Refractory Cancer Trials
- Orphan Drug Designation in Soft Tissue Sarcomas Expands Company's Potential to Address Cancers with High Unmet Medical Need

CHICAGO and FORT WORTH, Texas, Sept. 11, 2024 (GLOBE NEWSWIRE) -- Actuate Therapeutics, Inc. (NASDAQ: ACTU) ("Actuate" or the "Company"), a clinical-stage biopharmaceutical company, focused on developing therapies for the treatment of high-impact, difficult-to-treat cancers through the inhibition of glycogen synthase kinase-3 beta (GSK-3β), announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for elraglusib, a novel GSK-3β inhibitor for treatment of soft tissue sarcoma (STS).

"We are pleased to receive the ODD from the FDA, which underscores elraglusib's potential to address the significant yet unmet medical needs for patients with advanced cancers," said Daniel Schmitt, President & Chief Executive Officer of Actuate. "Elraglusib is a leading GSK-3β inhibitor that has demonstrated a favorable safety profile and antitumor activity across several solid tumors including melanoma, Ewing sarcoma, colorectal and pancreatic cancers. We look forward to the continued development of elraglusib and working closely with regulators to deliver its promise to cancer patients."

According to the American Cancer Society, it is projected that in 2024 alone, approximately 13,590 new cases of soft tissue sarcoma will be diagnosed in the United States. Additionally, an estimated 5,200 individuals are expected to die from this disease1.

“Soft tissue sarcomas are a rare but heterogeneous mix of tumors with >70 histological subtypes identified to date making sarcoma difficult to treat. Surgery remains the most effective treatment for localized cancer with median survival approaching 50%. However, patients with metastatic disease have a median overall survival of less than 6-12 months and remain a therapeutic challenge. Doxorubicin, approved almost 50 years ago, remains the recommended 1st line systemic treatment despite exhibiting minimal antitumor activity highlighting the unmet medical need for patients with metastatic STS,” said Dr. Steven D. Reich, Senior VP, Clinical Development and Acting Chief Medical Officer of Actuate. “Preclinical studies have demonstrated that elraglusib induces significant STS cell apoptosis and synergistic effects with chemotherapy providing rationale for the clinical evaluation in metastatic STS.”

The FDA’s Orphan Drug Designation FDA Orphan Drug Designation is granted to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the United States. Orphan drug status provides benefits to drug developers, including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees, and seven years of post-approval marketing exclusivity.

1 American Cancer Society. Cancer Facts & Figures 2024. Atlanta: American Cancer Society; 2024.

About Actuate Therapeutics, Inc.

Actuate is a clinical-stage biopharmaceutical company focused on developing therapies for the treatment of high-impact, difficult-to-treat cancers. Actuate’s lead investigational drug product, elraglusib (a novel GSK-3β inhibitor), targets molecular pathways in cancer that are involved in promoting tumor growth and resistance to conventional cancer drugs such as chemotherapy including several DDR pathways. Elraglusib is designed to act as a mediator of anti-tumor immunity through the inhibition of NF-kB and regulates multiple immune checkpoints and immune cell function. For additional information, please visit the Company’s website at **http://www.actuatetherapeutics.com**.

Forward-Looking Statements

This press release contains forward-looking statements about us, including our clinical trials and development plans, and our industry. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or the negative of these terms or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All statements, other than statements related to present facts or current conditions or of historical facts, contained in this press release are forward-looking statements. Accordingly, these statements involve estimates, assumptions, substantial risks and uncertainties which could cause actual results to differ materially from those expressed in them, including but not limited to that clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and

outcomes, results of prior preclinical studies and early clinical trials are not necessarily predictive of future results, and elraglusib may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all; that we may not successfully enroll additional patients or establish or advance plans for further development; that elraglusib could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials or result in other negative consequences; our reliance on third parties to conduct our non-clinical studies and our clinical trials; our reliance on third-party licensors and ability to preserve and protect our intellectual property rights; that we face significant competition from other biotechnology and pharmaceutical companies; and our ability to fund development activities. In addition, any forward-looking statements are qualified in their entirety by reference to the factors discussed under the heading “Risk Factors” in our final prospectus filed with the SEC on August 13, 2024 pursuant to Rule 424(b)(4) under the Securities Act with respect to our Registration Statement on Form S-1 (File No. 333-279734) and other filings with the SEC. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

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Source: Actuate Therapeutics