CASI Announces First Patient Dosed in Phase 1/2 Clinical Trial of CID-103 in Immune Thrombocytopenia

BEIJING, China (January 6, 2025) – CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a biopharmaceutical company specializing in the development and commercialization of innovative therapeutic and pharmaceutical products announced that the first patient has been dosed in the Phase 1/2 trial to evaluate the safety and tolerability of CID-103 in adult patients with chronic Immune Thrombocytopenia (ITP) in China.

"Dosing the first patient in our phase 1/2 study marks a significant milestone for both CID-103 program and chronic ITP patients who have limited treatment options," said Dr. Wei-Wu He, Chairman and CEO of CASI, "The rapid execution underscores our commitment to accelerating clinical development. This phase 1/2 study is designed to deliver important safety and dose-response data, providing valuable insights to guide the future development of CID-103 for additional autoimmune indications with significant unmet medical needs."

CID-103 is a fully human IgG1 anti-CD38 monoclonal antibody recognizing a unique epitope that has demonstrated encouraging preclinical efficacy and safety profile compared to other anti-CD38 monoclonal antibodies.

About CASI Pharmaceuticals

CASI Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products in China, the United States, and throughout the world. The Company is focused on acquiring, developing, and commercializing products that augment its focus on hematology oncology therapeutics and therapeutics for organ transplant rejection and autoimmune disease, as well as other areas of unmet medical need. The Company intends to execute its plan to become a leader by launching medicines in the Greater China market, leveraging the Company's China-based regulatory and commercial competencies and its global drug development expertise. The Company's operations in China are conducted through its wholly owned subsidiary, CASI Pharmaceuticals (China) Co., Ltd., located in Beijing, China. More information on CASI is available at www.casipharmaceuticals.com.

CASI Forward-Looking Statements

This announcement contains forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," "confident" and similar statements. Among other things, the business outlook and quotations from management in this announcement, as well as the Company's strategic and operational plans, contain forward-looking statements. The Company may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the "SEC"), in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about the Company's beliefs and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties. A number of factors could cause actual results to differ materially from those contained in any forward-looking statement, including but not limited to the following: uncertainties related to the non-binding proposal to acquire the Company's certain business operations in China; the risk that we may be unable to continue as a going concern as a result of our inability to raise sufficient capital for our operational needs; the possibility that we may be delisted from trading on The Nasdaq Capital Market if we fail to satisfy applicable continued listing standards; the volatility in the market price of our ordinary shares; the risk of substantial dilution of existing shareholders in future share issuances; the difficulty of executing our business strategy on a global basis including China; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; legal or regulatory developments in China that adversely affect our ability to operate in China; our lack of experience in manufacturing products and uncertainty about our resources and capabilities to do so on a clinical or commercial scale; risks relating to the commercialization, if any, of our products and proposed products (such as marketing, safety,

regulatory, patent, product liability, supply, competition and other risks); our inability to predict when or if our product candidates will be approved for marketing by the U.S. Food and Drug Administration, European Medicines Agency, PRC National Medical Products Administration, or other regulatory authorities; our inability to receive approval for renewal of license of our existing products; the risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; the risks associated with our product candidates, and the risks associated with our other early-stage products under development; the risk that result in preclinical and clinical models are not necessarily indicative of clinical results; uncertainties relating to preclinical and clinical trials, including delays to the commencement of such trials; our ability to protect our intellectual property rights; the lack of success in the clinical development of any of our products; and our dependence on third parties; the risks related to our dependence on Juventas to conduct the clinical development of CNCT19 and to partner with us to co-market CNCT19; risks related to our dependence on Juventas to ensure the patent protection and prosecution for CNCT19; the risk related to the Company's ongoing development of and regulatory application for CID-103 with respect to the treatment of antibody-mediated rejection for organ transplant and the license arrangements of CID-103; risks relating to interests of our largest shareholder and our Chairman and CEO that differ from our other shareholders; and risks related to the development of a new manufacturing facility by CASI Pharmaceuticals (Wuxi) Co., Ltd. Further information regarding these and other risks is included in the Company's filings with the SEC. All information provided herein is as of the date of this announcement, and the Company undertakes no obligation to update any forward-looking statement, except as required under applicable law. We caution readers not to place undue reliance on any forward-looking statements contained herein.

EVOMELA® is *proprietary to Acrotech Biopharma Inc. and its affiliates. FOLOTYN®* is *proprietary to Acrotech Biopharma Inc and its affiliates. Please refer to the Company's earlier SEC filing with respect to Evomela® for further information.*

COMPANY CONTACT:
Rui Zhang
CASI Pharmaceuticals, Inc.
240.864.2643
ir@casipharmaceuticals.com