CLEAVE THERAPEUTICS LICENSES FIRST-IN-CLASS VCP/P97 INHIBITOR CB-5339 TO CASI PHARMACEUTICALS FOR GREATER CHINA REGION

~ CASI's pipeline expanded to include first-in-class VCP/p97 inhibitor in Phase 1 for hematological malignancies and solid tumors ~

~ Cleave to receive $5.5 million upfront in cash payment and $5.5 million as a convertible note with potential to receive up to $74 million in milestone payments, plus tiered royalties ~

San Francisco, CA, and Rockville, MD – March 8, 2021 – Cleave Therapeutics, Inc. ("Cleave"), a clinical-stage biopharmaceutical company focused on valosin-containing protein (VCP)/p97 as a novel target in protein homeostasis, DNA damage response and other cellular stress pathways for therapeutic use in cancer, and CASI Pharmaceuticals, Inc (NASDAQ: CASI), a U.S. biopharmaceutical company with an established clinical development and commercial infrastructure in China, today announced they have entered an exclusive licensing agreement for the development and commercialization of CB-5339, a novel VCP/p97 inhibitor, in mainland China, Taiwan, Hong Kong and Macau.

Under the terms of the agreement, Cleave and CASI will develop CB-5339 in both hematological malignancies and solid tumors, with CASI responsible for development and commercialization in China and associated markets. Cleave will receive a $5.5 million upfront payment and is eligible to receive up to $74 million in development and commercial milestone payments plus tiered royalties in the high-single to mid-double-digit range on net sales of CB-5339. In addition to the upfront cash payment, CASI will make a $5.5 million investment in Cleave through a convertible note.

CB-5339, an oral second-generation, small molecule VCP/p97 inhibitor, is being evaluated in a Phase 1 clinical trial in patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), while the National Cancer Institute (NCI) is sponsoring and evaluating CB-5339 in a Phase 1 clinical trial of patients with solid tumors and lymphomas.

"Our collaboration with CASI is a strategic step to accelerate the development of CB-5339 globally by initiating trials for additional indications such as multiple myeloma in Greater China," said Amy Burroughs, President and CEO of Cleave Therapeutics. "CASI's development and commercial capabilities in hematology oncology and long-term commitment as an investor make them an ideal partner at this exciting time in the development of our first-in-class drug candidate."

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, said: "Cleave's novel approach to inhibiting VCP/p97 in hematological malignancies such as AML and MDS is supported by extensive preclinical research and early clinical data. CB-5339 represents a promising new agent for selectively targeting VCP/p97 in cancers and is a complementary addition to our growing portfolio of approved and investigational therapies for hematology oncology. We are thrilled to partner with Cleave as CB-5339 advances through clinical development."

About Cleave Therapeutics

Cleave Therapeutics is a clinical-stage biopharmaceutical company focused on VCP/p97 as a novel target in protein homeostasis and cellular stress pathways for therapeutic use in cancer. The privately held company, based in San Francisco, is studying CB-5339, its second-generation, small molecule VCP/p97 inhibitor, in a Phase 1 clinical trial in patients with acute myeloid leukemia and myelodysplastic syndrome, while the National Cancer Institute is sponsoring and evaluating CB-5339 in a Phase 1 clinical trial of patients with solid tumors and lymphomas. Cleave investors include 5AM Ventures, Bristol-Myers Squibb,

Orbimed, U.S. Venture Partners (USVP), Arcus Ventures, Astellas Venture Management, and Osage University Partners. For additional information, visit www.cleavetherapeutics.com.

About CASI Pharmaceuticals

CASI Pharmaceuticals, Inc. is a U.S. 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 hematology oncology therapeutic focus as well as other areas of unmet medical need. The Company is executing its plan to become a biopharmaceutical leader in the greater China market by leveraging the Company's China-based clinical, 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., which is located in Beijing, China. The Company has built a commercial team of more than 80 hematology and oncology sales and marketing specialists based in China. More information on CASI is available at www.casipharmaceuticals.com.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act with respect to the outlook for expectations for future financial or business performance, revenue growth, strategies, expectations and goals. Forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Forward-looking statements speak only as of the date they are made, and we assume no duty to update forward-looking statements. 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. Actual results could differ materially from those currently anticipated due to a number of factors.

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