

CASI PHARMACEUTICALS ANNOUNCES FIRST QUARTER 2021 FINANCIAL RESULTS

- *EVOMELA First Quarter 2021 Revenue Continues Upward Trend; Poised to Meet Greater Than 50% Revenue Growth Guidance in 2021 -*
- *Expands Pipeline with First-In-Class VCP/p97 Inhibitor for Hematological Malignancies and Solid Tumors -*
- *Registration Trials for Commercial Asset CNCT-19 (CD19 CAR-T) Progressing Well with NDA filings in China Expected by Juventas in 2021 -*

- *Company to Host Conference Call Today at 8:00 AM ET –*

ROCKVILLE, MD., and BEIJING, CHINA (May 13, 2021) CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products, today reported financial results for the first quarter of 2021.

Wei-Wu He, Ph.D., CASI's Chairman, and Chief Executive Officer, commented, "We are pleased to report \$5.7 million EVOMELA[®] revenues for the quarter. For the full year 2021, we expect to meet our guidance of greater than 50% revenue growth. In addition to upward trend in EVOMELA revenue, our first quarter was marked by our new China partnership with Cleave Therapeutics for CB-5339, an exciting first-in-class VCP/p97 inhibitor being investigated for hematological malignancies and solid tumors. We also completed a \$32.5 million capital raise at the end of March, from new fundamentally-driven, healthcare-dedicated investors, to strengthen our balance sheet."

Dr. He continued, "I am thrilled with the progress we are seeing across our hematology oncology product portfolio. With respect to our commercial asset CNCT-19 (CD19 CAR-T), our partner Juventas is making excellent progress with their current registration trials in B-NHL and B-ALL and is expecting to file NDAs in China by the end of 2021. Our CID-103 (anti-CD38 monoclonal antibody) Phase I trial remains on track with first patient dosing expected later this month, BI-1206 (anti-FcyRIIB monoclonal antibody) is on track with our China IND submission expected this year. We are excited by our momentum and will continue to execute on a number of key milestones across our broad portfolio in the quarters ahead."

First Quarter 2021 Financial Results

- Revenues consisted primarily of product sales of EVOMELA that launched in August of 2019. Revenue was \$5.7 million for the three months ended March 31, 2021, compared with \$3.4 for the three months ended March 31, 2020.
- Costs of revenues were \$2.4 million for the quarter ended March 31, 2021, compared with \$3.2 for the quarter ended March 31, 2020. The decrease in cost of revenues is due to the new alternate manufacturer now in place, resulting in a considerable decrease in the unit cost of inventories of EVOMELA. The decrease was partially offset by the continued growth in EVOMELA sales.
- Research and development expenses for the three months ended March 31, 2021 were \$5.3 million, compared with \$3.0 million for the three months ended March 31, 2020. The increases in R&D expenses are primarily due to an increase in R&D expenses incurred related to the development of CID-103. Included in our research and development expenses for the three months ended March 31, 2021 are direct project costs of \$3.5 million for preclinical development activities, primarily related to our CID-103 program, \$0.5 million related to our ANDAs acquired in 2018, and \$0.4 million for drugs in-licensed from Acrotech (previously Spectrum).
- General and administrative expenses for the first quarter of 2021 were \$5.5 million, compared with \$4.1 million for the same period in 2020. The increase in general and administrative expenses was primarily due

to an increase in headcount and payroll expenses as the Company continues to build its sales and marketing force.

- Selling and marketing expenses for the first quarter 2021 were \$2.7 million, compared with \$1.3 for the same period in 2020.
- Net loss for the first quarter of 2021 was \$13.7 million compared to \$8.2 million for the same period in 2020.
- As of March 31, 2021, the Company had cash and cash equivalents of \$68.1 million compared to \$57.1 million as of December 31, 2020.

Further information regarding the Company, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, can be found at www.casipharmaceuticals.com.

Conference Call

The Company will host a conference call reviewing the first quarter highlights at 8:00 a.m. ET on Thursday, May 13, 2021. On the call, CASI's Chairman & CEO will provide an update on the Company's business and upcoming milestones. The conference call can be accessed by dialing (833) 420-0382 (U.S.), 8008700181 (China), 58086567 (Hong Kong) to listen to the live conference call. The conference ID number for the live call is 7478587.

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 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., 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, 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 no duty to update forward-looking statements is assumed. Actual results could differ materially from those currently anticipated due to a number of factors, including: 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; the volatility in the market price of our common stock; the outbreak of the COVID-19 pandemic and its effects on global markets and supply chains; the risk of substantial dilution of existing stockholders in future stock issuances; the difficulty of executing our business strategy in China; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; 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 (FDA), National Medical Products Administration (NMPA), or other regulatory authorities; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; 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; our ability to design and implement a development plan for our ANDAs held by CASI Wuxi; 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; risks relating to the commercialization, if any, of our proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); risks relating to interests of our largest stockholders and our Chairman and CEO that differ from our other stockholders; and risks related to the development of a new manufacturing facility by CASI Wuxi. Such factors, among others, could have a material adverse effect upon our business, results of operations, and financial condition. We caution readers not to place undue reliance on any forward-looking statements, which only speak as of the date made. Additional information about the factors and risks that could affect our business, financial condition, and results of operations, are contained in our filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

EVOMELA® is proprietary to Acrotech Biopharma LLC and its affiliates.

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(Financial Table Follows)

CASI Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 68,117	\$ 57,064
Investment in equity securities, at fair value	10,948	9309
Accounts receivable, net of \$0 allowance for doubtful accounts	5,838	4,645
Inventories	2994	1,356
Prepaid expenses and other	1,117	1,651
Total current assets	<u>89,014</u>	<u>74,025</u>
Property, Plant and equipment, net	1876	2062
Intangible assets, net	12,834	13,210
Long-term investments	34,870	29,442
Right of use assets	8,323	8,696
Other assets	1176	299
Total assets	<u>\$ 148,093</u>	<u>\$ 127,734</u>
LIABILITIES, REDEEMABLE NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,741	\$ 3,669
Accrued and other current liabilities	2,238	3,015
Bank borrowings	1,525	826
Notes Payable	466	466
Total current liabilities	<u>9,970</u>	<u>7,976</u>
Deferred income	2,331	2,351
Other liabilities	13,596	13,834
Total liabilities	<u>25,897</u>	<u>24,161</u>
Commitments and contingencies		
Redeemable noncontrolling interest, at redemption value	22,164	22,033
Stockholders' equity:		
Preferred stock, \$1.00 par value: 5,000,000 shares authorized and 0 shares issued and outstanding	—	—
Common stock, \$0.01 par value: 250,000,000 shares authorized at March 31, 2021 and December 31, 2020; 139,877,032 and 124,023,374 shares issued at March 31, 2021 and December 31, 2020, respectively;	1,399	1,240
139,797,487 shares and 123,943,829 shares outstanding at March 31, 2021 and December 31, 2020, respectively		
Additional paid-in capital	690,018	658,246
Treasury stock, at cost: 79,545 shares held at September 30, 2020 and December 31, 2019	(8,034)	(8,034)
Accumulated other comprehensive loss	485	589
Accumulated deficit	(583,836)	(570,501)
Total stockholders' equity	<u>100,032</u>	<u>81,540</u>
Total liabilities, redeemable noncontrolling interest and stockholders' equity	<u>\$ 148,093</u>	<u>\$ 127,734</u>

CASI Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Product sales	\$ 5,700	\$ 3,372
Lease income	36	34
Total revenues	5,736	3,406
Costs and expenses:		
Costs of revenues	2,358	3,211
Research and development	5,258	3,017
General and administrative	5,502	4,058
Selling and marketing	2,715	1,260
Gain on disposal of intangible assets	0	(450)
Acquired in-process research and development	5,500	1,081
Total costs and expenses	21,333	12,177
Loss from operations	(15,597)	(8,771)
Non-operating income/(expense):		
Interest income, net	106	190
Other income	20	-
Foreign exchange gains	219	363
Change in fair value of investments	1,568	(15)
Net loss	(13,684)	(8,233)
Less: loss attributable to redeemable noncontrolling interest	(349)	(109)
Accretion to redeemable noncontrolling interest redemption value	548	317
Net loss attributable to CASI Pharmaceuticals, Inc.	\$ (13,883)	\$ (8,441)
Net loss per share (basic and diluted)	\$ (0.11)	\$ (0.09)
Weighted average number of common shares outstanding (basic and diluted)	124,825	98,773
Comprehensive loss:		
Net loss	\$ (13,684)	\$ (8,233)
Foreign currency translation adjustment	(172)	(826)
Total comprehensive loss	\$ (13,856)	\$ (9,059)
Less: Comprehensive loss attributable to redeemable noncontrolling interest	(417)	(109)
Comprehensive loss attributable to common stockholders	\$ (13,439)	\$ (8,950)