CASI Pharmaceuticals Acquires ANDA Portfolio From Sandoz Inc. (Sandoz)

ROCKVILLE, Md., Jan. 26, 2018 - CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a biopharmaceutical company dedicated to bringing quality pharmaceutical products to the Chinese and U.S. markets announced today that it has acquired a portfolio of 25 U.S. FDA-approved abbreviated new drug applications (ANDAs), one ANDA that FDA tentatively approved, and three ANDAs that are pending FDA approval. CASI intends to select and commercialize certain products from the portfolio that have unique market opportunity and cost-effective manufacturing in China and/or in the U.S.

Ken Ren, Ph.D., CASI's Chief Executive Officer commented, "The acquisition of the Sandoz ANDAs enhances our strategic focus to build a robust pipeline and commercialize quality drug candidates in China, including entecavir, an antiviral medication used in the treatment of hepatitis B viral infection ("HBV"), which unfortunately in China accounts for more than half of the estimated 700,000 HBV-related deaths worldwide each year. With FDA-approved ANDA status and the high-quality standards of Sandoz, we anticipate leveraging the Chinese FDA's (CFDA) more recent regulations to accept western pharmaceutical and clinical data for rapid entry into China's market while being competitive in the marketplace."

Dr. Ren continued, "This is an exciting and unprecedented time in the CFDA regulatory landscape, against a backdrop of soaring demand in China for high quality import pharmaceuticals. We are confident in our ability to launch certain products that we acquired from the Sandoz portfolio in China, along with our launch of EVOMELA®, MARQIBO® and ZEVALIN® all of which are in various stages of CFDA review. We look forward to completing our Company's transition from research and development to commercial."

About CASI Pharmaceuticals, Inc.

CASI is a U.S. based, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of therapeutics addressing cancer and other unmet medical needs for the global market with a focus on commercialization in China. CASI's product pipeline features (1) EVOMELA®, MARQIBO®, ZEVALIN®, all U.S. Food and Drug Administration (FDA) approved drugs in-licensed from Spectrum Pharmaceuticals, Inc. for China regional rights, and currently in various stages in the regulatory process for market approval in China, (2) an acquired portfolio of 25 FDA-approved ANDAs, 4 ANDAs that are pending FDA approval, from which CASI will prioritize a select subset of product registration and commercialization in China, (3) our proprietary drug candidate, ENMD-2076, currently in Phase 2 clinical development, and (4) proprietary early-stage candidates in preclinical development. CASI is headquartered in Rockville, Maryland and has a wholly owned subsidiary and R&D operations in Beijing, China. More information on CASI is available at www.casipharmaceuticals.com and in the Company's filings with the U.S. Securities and Exchange Commission.

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: 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 volatility in the market price of our common stock; risks relating to interests of our largest stockholders that differ from our other stockholders; the risk of substantial dilution of existing stockholders in future stock issuances, the difficulty of executing our business strategy in China; our inability to predict when or if our product candidates will be approved for marketing by CFDA authorities; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; risks associated with our product candidates; risks associated with any early-stage products under development; the risk that results in preclinical models are not necessarily indicative of clinical results; uncertainties relating to preclinical and clinical trials, including delays to the commencement of such trials; the lack of success in the clinical development of any of our products; dependence on third parties; and risks relating to the commercialization, if any, of our proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks). 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.