



September 18, 2014

## Spectrum Pharmaceuticals Out-Licenses Rights for Greater China to CASI Pharmaceuticals for Three of Its Drugs

- **Spectrum receives a 19.99% stake (pre-transaction) in CASI, a NASDAQ-listed, oncology-focused Company with expertise and focus on markets in China and a \$1.5 million promissory note**

HENDERSON, Nev. & ROCKVILLE, Md.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals, Inc. (Nasdaq: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, and CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a biopharmaceutical company dedicated to the acquisition, development and commercialization of innovative therapeutics addressing cancer and other unmet medical needs for the global market with a primary focus on China, announce the signing of license agreements whereby CASI has been granted exclusive rights to two of Spectrum Pharmaceuticals' commercial oncology drugs, Zevalin® (ibrutinib) Injection for intravenous use and Marqibo® (vinorelbine sulfate LIPOSOME injection) for intravenous infusion, and a Phase 3 drug candidate, Captisol-Enabled™ Melphalan (CE melphalan), for development and commercialization in China, including Taiwan, Hong Kong and Macau.

ZEVALIN is used in the treatment of non-Hodgkin's lymphoma (NHL) and MARQIBO is used in the treatment of acute lymphoblastic leukemia (ALL). CE melphalan has met the endpoints in a pivotal trial for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma. Spectrum plans to file a New Drug Application with the U.S. Food and Drug Administration (FDA) for CE melphalan in the second half of 2014.

CASI will be responsible for the development and commercialization of the three drugs, including the submission of import drug registration applications to regulatory authorities and conducting any confirmatory clinical studies in greater China, if and as required.

"We are delighted to see our anticancer drugs to be developed and marketed in greater China through CASI, a NASDAQ-listed Company focused on China," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "The management of CASI has a track record of successfully developing anticancer drugs in China. We are pleased to be a shareholder of CASI at this early stage of their development and look forward to CASI creating value for our shareholders as they grow. China's pharmaceutical market is growing at a rapid pace and is already approaching second place to only the United States in the world. The greater China drug market for anticancer drugs is projected to become the world's largest in the next decade and CASI has the opportunity to take a leading position to address these significant unmet medical needs. We are impressed with the management team at CASI and their expertise in China, and look forward to sharing in the success of our drugs in this important market."

Commenting on the transaction, Ken K. Ren, Ph.D., CASI's Chief Executive Officer, said, "We are very excited to have entered into this transaction with Spectrum, a Company with a successful track record of developing and commercializing drugs expeditiously in the U.S. The addition of these three drugs transforms our pipeline and significantly expands our market share potential in China. Our transaction is structured rather uniquely in that the shares and note represent the purchase price to Spectrum and is in lieu of royalties and milestones normally associated with traditional licenses, thereby aligning Spectrum's interest with our shareholders. We look forward to a productive relationship with Spectrum."

Dr. Ren added, "These drug products come with strong intellectual property protection and significant technology barriers. We are currently preparing the import drug registration applications in greater China, initially for ZEVALIN and MARQIBO, and since both drugs are approved for sale in the U.S., we anticipate that confirmatory clinical trials will be required for marketing approval in our territory. The submission of the import drug registration for CE melphalan will follow immediately after its approval by the U.S. FDA. The annual incidence in China for NHL, ALL and multiple myeloma is increasing each year with high mortality rates, it is our goal to have these innovative products available to patients in greater China as soon as possible to address these unmet medical needs, and as Spectrum expands these drugs into additional indications in the U.S., we too will apply for expanded labels in our territory."

In addition to its initial stake in CASI, Spectrum Pharmaceuticals will have certain rights to maintain its post-transaction ownership position. Spectrum Pharmaceuticals also will have the opportunity to designate a member to CASI's board of directors. Detailed information on the transaction can be found in CASI's Report on Form 8-K, which will be filed with the Securities and Exchange Commission.

H.C. Wainwright & Co., LLC acted as Spectrum's advisor.

### **About Spectrum Pharmaceuticals, Inc.**

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in oncology and hematology. Spectrum and its affiliates market five oncology drugs: FUSILEV® (levoleucovorin) for Injection; FOLOTYN® (pralatrexate injection); ZEVALIN® (ibrutinomab tiuxetan) Injection for intravenous use; MARQIBO® (vinCRISTine sulfate LIPOSOME injection) for intravenous infusion; and BELEODAQ™ (belinostat) for Injection. Spectrum's strong track record in in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at [www.sppirx.com](http://www.sppirx.com).

### **About CASI Pharmaceuticals, Inc.**

CASI is a biopharmaceutical company dedicated to the acquisition, development and commercialization of innovative therapeutics addressing cancer and other unmet medical needs for the global market with a primary focus on China. CASI's product pipeline includes exclusive regional rights to ZEVALIN (ibrutinomab tiuxetan), MARQIBO (vinCRISTine sulfate LIPOSOME injection) and Captisol-Enabled (propylene glycol-free) melphalan (CE melphalan) in greater China (including Taiwan, Hong Kong and Macau). CASI's development pipeline also includes its proprietary drug candidate ENMD-2076, a selective angiogenic kinase inhibitor currently in multiple Phase 2 oncology studies, and 2ME2 (2-methoxyestradiol) currently under reformulation 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](http://www.casipharmaceuticals.com) and in the Company's filings with the U.S. Securities and Exchange Commission.

### **About ZEVALIN and the ZEVALIN Therapeutic Regimen**

ZEVALIN (ibrutinomab tiuxetan) injection for intravenous use, is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL). ZEVALIN is also indicated for the treatment of patients with previously untreated follicular non-Hodgkin's Lymphoma who achieve a partial or complete response to first-line chemotherapy.

ZEVALIN is a CD20-directed radiotherapeutic antibody. The ZEVALIN therapeutic regimen consists of two components: rituximab, and Yttrium-90 (Y-90) radiolabeled ZEVALIN for therapy. ZEVALIN builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope.

#### ***Important ZEVALIN Safety Information***

Deaths have occurred within 24 hours of rituximab infusion, an essential component of the ZEVALIN therapeutic regimen. These fatalities were associated with hypoxia, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation, or cardiogenic shock. Most (80%) fatalities occurred with the first rituximab infusion. ZEVALIN administration can result in severe and prolonged cytopenias in most patients. Severe cutaneous and mucocutaneous reactions, some fatal, can occur with the ZEVALIN therapeutic regimen.

Please see full Prescribing Information, including BOXED WARNINGS, for ZEVALIN and rituximab. Full prescribing information for ZEVALIN can be found at [www.ZEVALIN.com](http://www.ZEVALIN.com).

### **About MARQIBO**

MARQIBO is a novel, sphingomyelin/cholesterol liposome-encapsulated, formulation of vincristine sulfate. Vincristine, a microtubule inhibitor, is FDA-approved for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. (The encapsulation technology, utilized in this formulation, has been shown to provide prolonged circulation of vincristine in the blood).

**Please see important safety information below and the full prescribing information for MARQIBO at [www.marqibo.com](http://www.marqibo.com).**

#### **Indication and usage**

MARQIBO is a liposomal vinca alkaloid indicated for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. This indication is based on overall response rate. Clinical benefit such as improvement in overall survival has not been verified.

## Important safety information

### CONTRAINDICATIONS

- MARQIBO is contraindicated in patients with demyelinating conditions including Charcot-Marie-Tooth syndrome
- MARQIBO is contraindicated in patients with hypersensitivity to vincristine sulfate or any of the other components of MARQIBO (vinCRISStine sulfate LIPOSOME injection)
- MARQIBO is contraindicated for intrathecal administration

### About Captisol-Enabled Melphalan

Captisol-enabled, PG-free melphalan is a novel intravenous formulation of melphalan being investigated for the multiple myeloma transplant setting, for which it has been granted an Orphan Drug Designation by the FDA. This formulation eliminates the use of propylene glycol, which has been reported to cause renal and cardiac side effects that limit the ability to deliver higher doses of therapeutic compounds. The use of the Captisol technology to reformulate melphalan also improves its stability and is anticipated to allow for slower infusion rates and longer administration durations, potentially enabling clinicians to safely achieve a higher dose intensity for pre-transplant chemotherapy.

### About Captisol

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled seven FDA-approved products, including Onyx Pharmaceuticals' Kyprolis<sup>®</sup>, Baxter International's Nexterone<sup>®</sup> and Merck's NOXAFIL IV. There are also more than 30 Captisol-enabled products currently in clinical development.

### Forward-Looking Statements - Spectrum Pharmaceuticals, Inc.

*This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to our business and its future, including sales of Spectrum's drug products, certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, leveraging the expertise of partners and employees around the world to assist us in the execution of our strategy, and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that our existing and new drug candidates may not prove safe or effective, the possibility that our existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of sustained revenue history, our limited marketing experience, our customer concentration, the possibility for fluctuations in customer orders, evolving market dynamics, our dependence on third parties for clinical trials, manufacturing, distribution, information and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law.*

SPECTRUM PHARMACEUTICALS, INC.<sup>®</sup>, FUSILEV<sup>®</sup>, FOLOTYN<sup>®</sup>, ZEVALIN<sup>®</sup>, and MARQIBO<sup>®</sup> are registered trademarks of Spectrum Pharmaceuticals, Inc. and its affiliates. BELEODAQ<sup>™</sup>, REDEFINING CANCER CARE<sup>™</sup> and Spectrum Pharmaceuticals logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

© 2014 Spectrum Pharmaceuticals, Inc. All Rights Reserved.

### Forward-Looking Statements - CASI Pharmaceuticals, Inc.

*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 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 candidate 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](http://www.sec.gov).*

**SPECTRUM INVESTORS:**

Spectrum Pharmaceuticals, Inc.  
Shiv Kapoor, 702-835-6300  
Vice President, Strategic Planning & Investor Relations  
[InvestorRelations@sppirx.com](mailto:InvestorRelations@sppirx.com)

or

**CASI INVESTORS:**

CASI Pharmaceuticals, Inc.  
240-864-2643  
[ir@casipharmaceuticals.com](mailto:ir@casipharmaceuticals.com)  
or  
LHA  
Kim Sutton Golodetz, 212-838-3777  
[kgolodetz@lhai.com](mailto:kgolodetz@lhai.com)

Source: Spectrum Pharmaceuticals, Inc.

News Provided by Acquire Media