Spectrum Pharmaceuticals Announces Results of Apaziquone Phase 3 Clinical Trials

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology, today announced that the two double blind, randomized, placebo controlled, Phase 3 clinical trials for apaziquone did not meet their primary endpoint of a statistically significant difference in the rate of tumor recurrence at 2 years between the two arms. However, analysis of the pooled data from both studies showed a statistically significant treatment effect in favor of apaziquone in the primary endpoint of the rate of tumor recurrence at 2 years (p-value = 0.0174) and in a key secondary endpoint, time to recurrence (p-value = 0.0076). The company is considering to request a meeting with the FDA to discuss future steps.

Apaziquone is a novel anticancer drug that is activated, to become a cytotoxic alkylating agent, by bio-reductive enzymes, such as DT-diaphorase, that are over-expressed in bladder cancer cells. Spectrum conducted two multi-center, Phase 3 trials of single dose intravesical instillation of apaziquone into the bladder in the immediate post-operative period after surgical resection of low-grade, non-muscle invasive bladder tumors (NMIBC). Patients were randomized to apaziquone or placebo. Under the protocol, the patients received a single 4 mg dose of apaziquone or placebo following TURBT (Trans-Urethral Resection of Bladder Tumor).

No drugs have been approved and marketed in the US for more than 20 years for low-grade NMIBC.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals, a biotechnology company with a primary focus in oncology and hematology, currently markets two oncology drugs, FUSILEV® (levoleucovorin) for Injection and ZEVALIN®(ibritumomab tiuxetan) Injection for intravenous use. In addition, Spectrum has two drugs, apaziquone and belinostat, in late stage development. The Company also has a diversified pipeline of novel drug candidates. The Company's strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial drug products. The Company has aggressive business development and commercial operation teams that support a robust drug development program encompassing clinical development, medical research, regulatory affairs, biostatistics and data management. The Company also leverages the expertise of its worldwide partners to assist in the execution of its strategy. For more information, please visit the Company's website at www.sppirx.com.

Forward-looking statement — 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 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 may not receive approval, and other regulatory agencies 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 dependence on third parties for clinical trials, manufacturing, distribution 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.

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Source: Spectrum Pharmaceuticals, Inc.