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Spectrum Pharmaceuticals Announces Agreement with FDA on the Special Protocol Assessment (SPA) for the Upcoming Apaziquone Phase 3 Trial in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC)

- **Company is on Track for Apaziquone NDA Filing by Year End Based on Pooled Data from Two Completed Phase 3 Studies that Showed a Statistically Significant Reduction in 2-Year Recurrence Rates (p-value = 0.0218)**
- **Learnings From Earlier Phase 3 Program and FDA's Comments Incorporated in New Phase 3 Study Design**
- **New Phase 3 Study Would Satisfy FDA's Requirement of Initiating an Additional Phase 3 Study Before Apaziquone NDA Submission**
- **NMIBC is the Fifth Most Common Cancer in the U.S. With Highest Per Patient Cost and High Unmet Medical Need Due to High Recurrence Rates and No FDA-approved Agents**

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations and a primary focus in Hematology and Oncology, announced today that the company has reached agreement with the U.S. Food and Drug Administration (FDA) on the Special Protocol Assessment (SPA) of the planned Phase 3 clinical trial of its novel, potent pro-drug, apaziquone. This trial will further evaluate the intravesical use of apaziquone for the treatment of patients with non-muscle invasive bladder cancer (NMIBC) as one or two instillations, immediately following transurethral resection of bladder tumor (TURBT).

"Spectrum's agreement with the FDA on the SPA represents a significant milestone for bladder cancer patients," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "The learnings from previous Phase 3 studies and comments from the FDA have been incorporated in the new protocol to improve the chances of success. We look forward to initiating this trial and filing the apaziquone NDA by year-end. This NDA is based on data from the previously completed program that included two Phase 3 studies with a total of 1,615 patients. We believe there continues to be a significant unmet need for these patients, as no drugs have been approved in the U.S. for more than 40 years for the treatment of low-grade NMIBC. Due to the high rate of recurrence, the overall cost of the treatment of bladder cancer in the U.S. is a staggering $3.4 billion annually, most of which is related to direct treatment of the disease. We endeavor to bring this much needed therapy for patients and help reduce overall medical costs at the same time."

In accordance with the SPA, the Phase 3 trial will be a randomized, double-blind, placebo-controlled, multicenter trial that will enroll patients with Ta G1 or G2 NMIBC. The patients will be randomized to receive either one instillation of apaziquone, two instillations of apaziquone, or placebo. The primary endpoint is Time to Recurrence. Since apaziquone is known to be inactivated in presence of blood, the new protocol includes a 30-60 minute waiting period post-TURBT, before apaziquone instillation. Patients that receive two instillations of apaziquone, will receive the second dose approximately two weeks after surgery minimizing the potential for drug inactivation due to bleeding. Further, it is recommended that patients with significant post-operative bleeding not receive apaziquone.

Apaziquone is an anticancer pro-drug that is activated by bio-reductive enzymes that are over-expressed in bladder cancer cells, rendering it into a highly cytotoxic alkylating agent. Spectrum has conducted two multi-center, international Phase 3 trials of a single intravesical instillation of apaziquone (4 mg) into the bladder in the immediate post-operative period after surgical resection of low-grade NMIBC. Pooled data from the two studies (n=1,615) showed a statistically significant treatment effect for the primary study endpoint, 2-Year Recurrence Rates, in favor of apaziquone (p-value = 0.0218) and in a key secondary endpoint, Time to Recurrence (p-value = 0.0096).

About Bladder Cancer

According to the National Cancer Institute, bladder cancer is the fifth most common malignancy in the US with 74,000 new cases of bladder cancer expected in 2015, and currently over 500,000 patients living with the disease. Due to high recurrence rates, intensive surveillance strategies, and expensive annual treatment costs, bladder cancer has the highest per patient costs, and an overall cost estimated at around $3.4 billion. Non-muscle invasive bladder cancer (NMIBC) is a form of bladder cancer that is localized in the surface layers of the bladder and has not invaded or spread to the deeper muscle layer. Approximately 70% of all patients newly diagnosed with bladder cancer have NMIBC. Urologists treat the disease predominantly by transurethral resection of the bladder tumor(s) (TURBT); in the U.S., there are approximately 300,000 TURBT procedures every year to treat

bladder cancer. Because of the high recurrence rates, both professional urology associations and NCCN Guidelines recommend instillation of a cytotoxic agent following TURBT for NMIBC, although in the U.S., there are no FDA-approved agents for this indication.

About Special Protocol Assessments

A Special Protocol Assessment is a written agreement between a Sponsor and the U.S. Food and Drug Administration on the design, execution and analysis for a clinical trial that may form the basis of a new drug application, or NDA. Final marketing approval depends upon the efficacy results, safety profile and an evaluation of the risk/benefit of treatment demonstrated in the Phase 3 clinical program.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in Hematology and Oncology. Spectrum markets five Hematology/Oncology drugs, and expects an FDA decision on another hematology drug later this year. Additionally, Spectrum's pipeline includes three drugs targeting blockbuster markets in advanced stages of clinical development. 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.

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 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 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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