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Spectrum Pharmaceuticals Initiates Apaziquone Pivotal Trial for the Treatment of Non-Muscle Invasive Bladder Cancer (NMIBC) Following SPA Agreement

- **Company on Track for Apaziquone NDA Filing Based on Prior Phase 3 Data by Year End**
- **Learnings From Prior Trials and Agreement with the FDA Through a Special Protocol Assessment (SPA) Incorporated into Study Design**
- **Pivotal 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 the Company has initiated the planned Phase 3 clinical study for apaziquone, its novel, potent pro-drug, and the first patient was dosed on Friday, October 23, 2015. Apaziquone is an alkylating agent being investigated as intravesical treatment to address the unmet medical need for patients with non-muscle invasive bladder cancer (NMIBC), administered as one or two instillations immediately following transurethral resection of bladder tumors (TURBT).

"Apaziquone has the potential to usher in an importantly needed paradigm shift in the treatment of NMIBC, as the first new drug in its indication in over 40 years," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "This Phase 3 study has been specifically designed to address important lessons learned from the previous apaziquone Phase 3 studies, as well as recommendations from the FDA that improve chances of a successful study outcome. Pooled data from the previously completed Phase 3 studies that enrolled over 1,600 patients, showed a statistically significant reduction in the 2-year Recurrence rate and strong safety data. These existing Phase 3 data form the basis of the NDA that we plan to submit to FDA before the end of the year. Because of the high frequency of recurrences, the overall cost for 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 are hopeful that we can get this drug to the market as soon as possible to meet the significant unmet medical need."

"I am impressed with the data and the activity of apaziquone in NMIBC that I have seen so far in clinical trials," said Lawrence Karsh, MD, FACS, Director of Research at The Urology Center of Colorado. "In bladder cancer patients, there is, unfortunately, a high rate of recurrence that necessitates frequent surgeries. Due to the high rate of recurrence, there is significant patient morbidity and the disease is expensive to treat. There is a strong scientific rationale for the use of a chemotherapeutic agent post-TURBT, and NCCN guidelines recommend the post-TURBT instillation of a chemotherapeutic agent. However, no drug has been specifically approved for post-TURBT instillation in the US for this group of patients. The addition of a new effective therapy for this recurring disease would help to address the high unmet medical need, offer patients an important new treatment option, and potentially reduce the healthcare costs associated with the treatment of NMIBC."

In accordance with the SPA agreement, this Phase 3 trial will be a randomized, double-blind, placebo-controlled, multicenter trial that will enroll patients with Ta, G1-G2 NMIBC. Patients will be randomized to receive either one instillation of apaziquone, two instillations of apaziquone, or placebo with a primary endpoint of Time to Recurrence. Since apaziquone is known to be inactivated in presence of blood, the new protocol requires the dosing of apaziquone in a 30-90 minute window post-TURBT. Patients randomized to receive two instillations of apaziquone, will receive the second dose approximately two weeks after surgery, further minimizing the potential for drug inactivation due to bleeding. In addition, the protocol recommends 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, randomized 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, i.e., a reduction in the 2-Year Recurrence Rate, 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 the high recurrence rate, intensive surveillance strategies, and expensive annual treatment costs, bladder cancer has the highest per patient costs with an overall cost estimated at around $3.4 billion. Non-muscle invasive bladder cancer 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 TURBT. In the U.S., there are approximately 300,000 TURBT procedures every year to treat bladder cancer. Because of the high recurrence rate, both professional urology associations and NCCN Guidelines recommend the 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 Oncology and Hematology. Spectrum and its affiliates market five oncology drugs– FUSILEV® (levoleucovorin) for Injection in the U.S.; FOLOTYN® (pralatrexate injection), also marketed in the U.S.; ZEVALIN® (ibritumomab tiuxetan) Injection for intravenous use, for which the Company has worldwide marketing rights; MARQIBO® (vinCRIStine sulfate LIPOSOME injection) for intravenous infusion, for which the Company has worldwide marketing rights,and BELEODAQ® (belinostat) for Injection in the U.S. 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 and proven track record 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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