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Spectrum Pharmaceuticals Announces Initiation of the Registrational Phase 3 Trial of Qapzola™ (apaziquone) in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC)

- **Qapzola is a novel drug activated by DT-diaphorase, an enzyme over-expressed in bladder cancer cells, to generate cytotoxic species leading to cell death.**
- **NMIBC is the fifth most common cancer in the U.S. with the highest lifetime cost per patient. It is an unmet medical need due to high recurrence rates and no FDA-approved drugs.**
- **Spectrum's registrational Phase 3 trial, being conducted under a new Special Protocol Assessment (SPA) agreement with the FDA, incorporates feedback from the FDA, key opinion leaders (KOLs) and learnings from earlier studies.**

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals, Inc. (NasdaqGS:SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in Hematology and Oncology, announced today the Company has enrolled the first patient in a Phase 3 trial of Qapzola, a potent tumor-activated drug being investigated for low and intermediate risk non-muscle invasive bladder cancer. Under the SPA, this trial will evaluate the intravesical use of Qapzola in patients with non-muscle invasive bladder cancer (NMIBC), as a single instillation 60 ± 30 minutes, following transurethral resection of the bladder tumor (TURBT).

"Qapzola is being developed for low-to-intermediate risk non-muscle invasive bladder cancer for which there are no approved drugs in the 21st century," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "This is a novel drug that becomes cytotoxic only when it encounters hypoxic tumor such as non-muscle invasive bladder cancer. Bladder tumors are rich in DT-diaphorase, an enzyme that converts Qapzola into an alkylating agent that leads to cell death. One of the key challenges in the treatment of bladder cancer is a significantly high recurrence rate which leads to exorbitant costs and high patient morbidity. It is estimated that the cost of treatment of this disease will surpass $5 billion by 2020. The design of the current trial incorporates learnings from previous studies, feedback from leading KOL's as well as from the FDA. I believe, Spectrum's pipeline has never been as exciting as it is today. In addition to aggressive development of Qapzola, we expect to file a registration application (BLA) with the FDA for Rolontis in 2018 and we are very excited with the early data we are seeing with Poziotinib, our novel irreversible tyrosine kinase inhibitor."

In accordance with the SPA, the Phase 3 trial is a randomized, double-blind, placebo-controlled, multi-center trial that will enroll patients with low and intermediate risk NMIBC as per the American Urology Association (AUA) Guidelines. The new study design with a reduced sample size from 1557 to about 425 patients will significantly shorten the duration of this trial. The protocol includes a single instillation of Qapzola 60 ± 30 minute post-TURBT, to avoid inactivation of Qapzola by blood that is present after surgery. The patients will be randomized 2:1 to receive either 8 mg instillation of Qapzola or placebo post-TURBT. Following one instillation of study drug and a safety follow-up at Day 35, subsequent follow up visits will be conducted until tumor recurrence or end of study, whichever occurs first. The primary endpoint for this trial is Time to Recurrence.

About Bladder Cancer

According to the National Cancer Institute, bladder cancer is the fifth most common malignancy in the US with 79,030 new cases of bladder cancer expected in 2017, 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 lifetime cost per patient of all cancers, 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 currently markets six hematology/oncology drugs, and has an advanced stage pipeline that has the potential to transform the Company. Spectrum's strong track record for 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 Spectrum's 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, the timing and results of FDA decisions, 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 Spectrum's 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 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. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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