Spectrum Pharmaceuticals Receives FDA Approval of KHAPZORY™ (levoleucovorin) for injection

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HENDERSON, Nev.--(BUSINESS WIRE)--Oct. 23, 2018-- Spectrum Pharmaceuticals, Inc. (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 U.S. Food and Drug Administration (FDA) has approved KHAPZORY (levoleucovorin) for injection, a folate analog for three indications:

• Rescue after high-dose methotrexate therapy in patients with osteosarcoma.

• Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination.

• The treatment of patients with metastatic colorectal cancer in combination with fluorouracil.

KHAPZORY is not indicated for the treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B12 because of the risk of progression of neurologic manifestations despite hematologic remission.

“KHAPZORY is the first levoleucovorin product approved by the FDA that contains sodium in its formulation,” said Joe Turgeon, President and Chief Executive Officer of Spectrum Pharmaceuticals. “This NDA submission was part of the lifecycle management of our legacy product, FUSILEV. Our focus remains on the development of novel, targeted therapeutics including poziotinib and ROLONTIS.”

Spectrum is currently evaluating strategic options on the launch of KHAPZORY. Product supply will be available in January.

Important Safety Information for KHAPZORY

Contraindications

• KHAPZORY is contraindicated in patients who have had severe hypersensitivity to leucovorin products, folic acid, or folinic acid.

Warnings and Precautions

• **Increased gastrointestinal toxicities with fluorouracil:** Gastrointestinal toxicities, including stomatitis and diarrhea, occur more commonly and may be of greater severity and of prolonged duration. Deaths from severe enterocolitis, diarrhea, and dehydration have occurred in elderly patients receiving

weekly *d,l*-leucovorin and fluorouracil. Do not initiate or continue therapy with KHAPZORY and fluorouracil in patients with symptoms of gastrointestinal toxicity until those symptoms have resolved. Monitor patients with diarrhea until it has resolved as rapid deterioration leading to death can occur.

• **Drug interaction with trimethoprim-sulfamethoxazole:** Concomitant use of *d,l*-leucovorin with trimethoprim-sulfamethoxazole for the acute treatment of Pneumocystis jiroveci pneumonia in patients with HIV infection increased treatment failure and morbidity.

Adverse Reactions

• The most common adverse reactions (?20%) in patients receiving high-dose methotrexate therapy with levoleucovorin rescue were stomatitis (38%) and vomiting (38%).

• The most common adverse reactions (>50%) in patients receiving levoleucovorin in combination with fluorouracil for metastatic colorectal cancer were stomatitis (72%), diarrhea (70%), and nausea (62%).

Drug Interactions

Leucovorin products increase the toxicity of fluorouracil.

Use in Specific Populations

Levoleucovorin is administered in combination with methotrexate or fluorouracil, which can cause embryo-fetal harm. Refer to methotrexate and fluorouracil prescribing information for additional information.

Please see full Prescribing Information for KHAPZORY available at KHAPZORY.com

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biopharmaceutical 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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Spectrum Pharmaceuticals, Inc.
Shiv Kapoor, 702-835-6300
Vice President, Strategic Planning & Investor Relations
InvestorRelations@sppirx.com