Spectrum Pharmaceuticals Announces Submission of Biologics License Application to the FDA for ROLONTIS® (eflapegrastim) as a Treatment for Chemotherapy-Induced Neutropenia

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- Submission based on results from two large, positive pivotal trials
- Both pivotal trials successfully met their primary endpoint and all secondary endpoints
- ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) that utilizes a proprietary platform technology to maximize the pharmacological activity of G-CSF

HENDERSON, Nev.--(BUSINESS WIRE)--Dec. 27, 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, announced today that the company submitted a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for ROLONTIS® (eflapegrastim).

"ROLONTIS is an important and significant future growth driver for our company," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Today's milestone brings us one step closer to bringing the first novel G-CSF to healthcare providers in over 15 years in a large market that is familiar to Spectrum."

The BLA for ROLONTIS is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive cytoxic chemotherapy. The study ADVANCE was conducted under a special protocol assessment (SPA) with the Agency. In both studies, ROLONTIS demonstrated the pre-specified hypothesis of non-inferiority (NI) in Duration of Severe Neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLONTIS also demonstrated non-inferiority to pegfilgrastim in the DSN across all 4 cycles (all NI $p<0.0001$) in both studies.

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 seven 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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