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Spectrum Pharmaceuticals Submits Phase 2 Breast Cancer Protocol to FDA as Part of an Investigational New Drug (IND) Application for Poziotinib

- **Spectrum Plans to Initiate a 70 Patient U.S. Based Breast Cancer Phase 2 Study as Soon as Possible**
- **Poziotinib Has Already Been Studied in Multiple Cancer Types in over 250 Patients and Has Shown Activity in Breast Cancer, Lung Cancer and Gastric Cancer**
- **Poziotinib Has Shown a Remarkable 60% Response Rate in Phase 1 Patients with Breast Cancer Who Had Previously Failed Multiple Lines of Treatment, Including the Her2-Directed Therapies Trastuzumab and Lapatinib**

HENDERSON, Nev.--(BUSINESS WIRE)-- Spectrum Pharmaceuticals (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 submitted an IND application to the U.S. Food and Drug Administration (FDA) and plans to initiate a Phase 2 breast cancer study in the U.S. as soon as possible.

"This Phase 2 study is an important step for us to solidify our registration strategy in the U.S.," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "The potential target market for Poziotinib is large, and metastatic breast cancer patients continue to progress despite availability of several drugs. Poziotinib has shown promising early clinical activity in Phase 1 trials in patients who had failed multiple lines of treatment including the HER2-directed therapies, trastuzumab and lapatinib. The U.S. Phase 2 trial was designed based on learnings from Phase 1 and Hanmi's ongoing Phase 2 trials in Korea. We are planning a fast to market strategy as a single agent in parallel with the development of a broader indication using poziotinib in combination with other approved therapies for use in earlier stage disease."

The Phase 2 study is planned to be an open-label study that will enroll approximately 70 patients with HER-2 positive metastatic breast cancer, who have failed at least one or more HER-2 directed therapy. The dose and schedule of oral poziotinib will be based on clinical experience from the studies in Korea, and in addition include the use of prophylactic therapies to help minimize known side-effects of HER2-directed therapies.

Poziotinib is a novel, oral pan-HER inhibitor that irreversibly blocks signaling through the Epidermal Growth Factor Receptor (EGFR, HER) Family of tyrosine-kinase receptors, including HER1 (erbB1; EGFR), HER2 (erbB2), and HER4 (erbB4), and importantly, also HER receptor mutations; this, in turn, leads to the inhibition of the proliferation of tumor cells that overexpress these receptors. Mutations or overexpression/amplification of EGFR family receptors have been associated with a number of different cancers, including non-small cell lung cancer (NSCLC), breast cancer, gastric cancer, etc. Currently, poziotinib is being investigated by Hanmi in several mid-stage trials in different solid tumor indications including EGFR-mutant NSCLC, gastric cancer, head & neck cancer and HER2 positive breast cancer.

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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