Spectrum Pharmaceuticals Presents Twice Daily Dosing Data for Poziotinib at the ESMO TAT Virtual Congress 2021

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HENDERSON, Nev.--(BUSINESS WIRE)--Mar. 2, 2021-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today presented results from Cohort 3 and initial twice daily (BID) dosing safety and efficacy data for poziotinib from Cohort 5 of the ZENITH20 clinical trial. These preliminary data demonstrate improved tolerability with BID dosing, reduced dose interruption compared to once daily (QD) dosing, and a reduction in treatment emergent Grade 3 or higher adverse events. The preliminary data also suggest improved anti-tumor activity with 8mg BID dosing. The presentation is part of the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO TAT) Virtual Congress 2021 being held March 1-2, 2021.

“As predicted by the pharmacokinetic modeling, the 8mg BID arm is showing an improved therapeutic effect and a lowered adverse event rate in this early data,” said Francois Lebel, M.D., Chief Medical Officer of Spectrum Pharmaceuticals. “The data build on the positive results we have reported for Cohort 2 which will be the basis for our NDA submission later this year. We look forward to reporting additional data at AACR in April.”

A copy of the ESMO presentation titled “Safety, tolerability and preliminary efficacy of poziotinib with twice daily strategy in EGFR/HER2 Exon 20 mutant non-small cell lung cancer” is available on Spectrum’s website at https://investor.sppirx.com/events-and-presentations.

ZENITH20 Trial Design and Preliminary Safety and Efficacy Data for Cohort 5

Cohort 5 of the ZENITH20 trial includes previously treated NSCLC patients with EGFR or HER2 exon 20 insertion mutations. This cohort is investigating the efficacy of poziotinib with a BID dosing strategy. For the first 20 patients randomized to poziotinib 16 mg QD or 8 mg BID in Cohort 5, a trend towards improved responses was reported in the BID arm with 30% of patients reaching a partial response and two patients still too early to evaluate.

Preliminary Data on Best Overall Response

	Cohort 1	**Cohort 5a**	**Cohort 5d**
	16mg QD	**16mg QD**	**8mg BID**
	N=10 (%)	**N=10 (%)**	**N=10 (%)**
PR - Partial Response	2 (20)	2 (20)	3 (30)
SD - Stable Disease	5 (50)	4 (40)	2 (20)
PD - Progressive Disease	2 (20)	0	1 (10)
NE - Not Evaluable (withdrawn)	1 (10)	4 (40)	2 (20)
NA - Too Early to Assess	0	0	2 (20)

Improved tolerability was also observed, with a greater than 30% reduction in Grade 3 or higher adverse events for the BID arms relative to QD. In addition, there were 23% fewer dose interruptions for 8mg BID vs 16mg QD and 43% fewer dose interruptions for 6mg BID vs 12mg QD.

BID Dosing Exposure and Safety

Preliminary Data (study enrolling)

	16mg QD	**8mg BID**	**12mg QD**	**6mg BID**

Enrolled	22	16	23	16
Drug Interruption, n (%)	18 (82)	10 (63)	20 (87)	8 (50)
Dose Reduction	13 (59)	8 (50)	13 (57)	6 (38)
Treatment Related AE ≥ Grade 3	10 (45)	5 (31)	9 (39)	3 (19)

While preliminary, these data support the hypothesis that BID dosing could improve the therapeutic effect for patients receiving poziotinib and result in better outcomes. Cohort 5 is continuing to enroll patients and a presentation of additional results is expected later this year at a medical conference.

About Poziotinib

Poziotinib is a novel, oral epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI) that inhibits the tyrosine kinase activity of EGFR as well as HER2 and HER4. Importantly 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, and gastric cancer. The company holds an exclusive license from Hanmi Pharmaceuticals to develop, manufacture, and commercialize poziotinib worldwide, excluding Korea and China. Poziotinib is currently being investigated by the company and Hanmi in several mid-stage trials in multiple solid tumor indications.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. Spectrum has a strong track record of successfully executing across the biopharmaceutical business model, from in-licensing and acquiring differentiated drugs, clinically developing novel assets, successfully gaining regulatory approvals and commercializing in a competitive healthcare marketplace. Spectrum has a late-stage pipeline with novel assets that serve areas of unmet need. This pipeline has the potential to transform the company in the near future. For additional information on Spectrum Pharmaceuticals please visit www.sppirx.com.

Notice Regarding Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These forward-looking statements relate to a variety of matters, including, without limitation, statements that relate to Spectrum's business and its future, including the significance of the preliminary dosing data for poziotinib, including the ability to achieve an improved therapeutic effect and a lowered adverse event rate with BID dosing; the company's plans to present additional study results at a medical conference later in the year; poziotinib's potential to significantly advance the treatment of NSCLC patients with EGFR or HER2 exon 20 insertion mutations; the timing and results of the company's planned NDA submission; the overall progression of the poziotinib development program; the company's ability to advance and fund the development and commercialization of its late-stage pipeline assets and such assets' ability to serve areas of unmet need; the future potential of the company's existing drug pipeline and its ability to transform the company in the near future; and other statements that are not purely statements of historical fact. These forward-looking statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Spectrum and are subject to significant risks and uncertainties that could cause actual results to differ materially from what may be expressed or implied in these forward-looking statements. Risks that could cause actual results to differ include, but are not limited to, the possibility that the different methodologies, assumptions and applications the company utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if the company believes the data collected from the clinical trials of its product candidates, including poziotinib, are positive, these data may not be sufficient to support approval by the FDA; the possibility that success in early clinical trials, especially if based on a small patient sample, might not result in success in later clinical trials, and other unforeseen events during clinical trials which could cause delays or other adverse consequences; other uncertainties inherent in new product development; the possibility that Spectrum's new and existing drug candidates, including poziotinib, may not ultimately prove to be safe or effective; the possibility that Spectrum's new and existing drug candidates, if approved, may not be more effective, safer, or more cost efficient than competing drugs; and other risks that are described in further detail in the company's reports filed with the Securities and Exchange Commission (the "SEC"). 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. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Spectrum in general, see the risk disclosures in the Annual Report on Form 10-K of Spectrum for the year ended December 31, 2019, and in subsequent reports on Forms 10-K, 10-Q and 8-K and other filings made with the SEC by Spectrum.

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