



Spectrum Pharmaceuticals Announces Positive Results from Phase 2 Trial Evaluating Use of Oral Leucovorin to Potentially Mitigate Mucositis in Patients Treated with FOLOTYN® (pralatrexate)

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- In practice, FOLOTYN use has caused Grade 2 or higher oral mucositis in more than half of patients, potentially impacting treatment of relapsed or refractory Peripheral T-cell Lymphoma (PTCL)
- This was the first prospective study to evaluate the effect of oral leucovorin in preventing or reducing FOLOTYN-related oral mucositis in patients with hematological malignancies, including PTCL and CTCL
- New data demonstrated FOLOTYN treatment with adjunct leucovorin has resulted in a significantly lower rate of \geq Grade 2 oral mucositis (5.7%) as compared to historical data (52%); no patient reported \geq Grade 3 oral mucositis
- No patient omitted, delayed or reduced FOLOTYN dose due to oral mucositis
- Data appeared in a poster at the 60th Annual Meeting of the American Society of Hematology (ASH)

HENDERSON, Nev.--(BUSINESS WIRE)--Dec. 3, 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 results from a prospective Phase 2 single-arm, open-label, multicenter clinical trial studying the management of oral mucositis with the use of oral leucovorin (*d,l*-folinic acid) as adjunct to FOLOTYN® (pralatrexate) in patients with hematological malignancies, including PTCL and CTCL. These new data were highlighted in a poster presentation at the 60th Annual Meeting of the American Society of Hematology (ASH).

Study results with a total of 35 patients demonstrated that use of leucovorin 25 mg tablets by oral administration for two days (a total of six doses [150 mg cumulative weekly dose]), initiated 24 hours after each FOLOTYN dose (30 mg/m² IV administration, once weekly for six weeks in each cycle) reduced the rate of Grade 2 or greater mucositis significantly, to 5.7 percent (95% CI = 1 – 19%) from historic rate (52%) associated with FOLOTYN use. There were no reports of \geq Grade 3 oral mucositis. Grade 1 oral mucositis was reported only in 4 (11%) patients. No patient omitted, delayed or reduced FOLOTYN dose due to oral mucositis with adjunct leucovorin therapy. The occurrence of mucositis, an impediment of FOLOTYN, has previously been reported at a rate of 52 percent at Grade 2 or higher in patients undergoing treatment with FOLOTYN in a registration study (PROPEL).¹

“Mucositis is a frequent complication of FOLOTYN therapy, which can cause painful inflammation of the digestive tract. It is often managed by omitting, delaying, or reducing the dose of this medication in some patients,” said Andrei R Shustov, MD, lead investigator, professor of medicine, hematology, University of Washington School of Medicine, and hematologist, Seattle Cancer Care Alliance. “We are excited about how significantly leucovorin was able to reduce the rate of mucositis in patients and believe this study established the foundation for the potential use of leucovorin as a preventive regimen for FOLOTYN patients.”

“While previous studies have established the use of FOLOTYN as an option in relapsed or refractory PTCL patients, mucositis has been an issue that could impact treatment and quality of life,” said Francois Lebel, MD, Chief Medical Officer, Spectrum Pharmaceuticals. “This is the first prospective study to suggest that leucovorin may prevent or reduce oral mucositis. These are welcome findings that merit further studies of leucovorin as an adjunct to FOLOTYN so we can one day provide definitive guidance to physicians to help reduce concerns of FOLOTYN treatment delay or discomfort due to oral mucositis.”

About FOLOTYN®

FOLOTYN, (pralatrexate injection), a folate analogue metabolic inhibitor, was discovered by Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute and developed by Allos Therapeutics. In September 2009, the U.S. Food and Drug Administration (FDA) granted accelerated approval for FOLOTYN for use as a single agent for the treatment of patients with relapsed or refractory PTCL. This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated. FOLOTYN has been available to patients in the U.S. since October 2009. An updated analysis of data from PROPEL, the pivotal study of FOLOTYN in patients with relapsed or refractory PTCL, was published in the March 20, 2011 issue of the Journal of Clinical Oncology.

Important FOLOTYN® Safety Information

Warnings and Precautions

FOLOTYN may suppress bone marrow function, manifested by thrombocytopenia, neutropenia, and anemia. Monitor blood counts and omit or modify dose for hematologic toxicities.

Mucositis may occur. If greater-than or equal to Grade 2 mucositis is observed, omit or modify dose. Patients should be instructed to take folic acid and receive vitamin B12 to potentially reduce treatment-related hematological toxicity and mucositis.

Fatal dermatologic reactions may occur. Dermatologic reactions may be progressive and increase in severity with further treatment. Patients with dermatologic reactions should be monitored closely, and if severe, FOLOTYN should be withheld or discontinued. Tumor lysis syndrome may occur. Monitor patients and treat if needed.

FOLOTYN can cause fetal harm. Women should avoid becoming pregnant while being treated with FOLOTYN and pregnant women should be informed of the potential harm to the fetus.

Use caution and monitor patients when administering FOLOTYN to patients with moderate to severe renal function impairment.

Elevated liver function test abnormalities may occur and require monitoring. If liver function test abnormalities are greater-than or equal to Grade 3, omit or modify dose.

Adverse Reactions

The most common adverse reactions were mucositis (70%), thrombocytopenia (41%), nausea (40%), and fatigue (36%). The most common serious adverse events are pyrexia, mucositis, sepsis, febrile neutropenia, dehydration, dyspnea, and thrombocytopenia.

Use in Specific Patient Population

Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

Drug Interactions

Co-administration of drugs subject to renal clearance (e.g., probenecid, NSAIDs, and trimethoprim/sulfamethoxazole) may result in delayed renal clearance.

Please see FOLOTYN Full Prescribing Information at www.FOLOTYN.com.

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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¹ O'Connor OA, Pro B, et al. Pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma: results from the pivotal PROPEL study. J Clin Onc. 2011; 29(9): 1182-1189.

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