



## Spectrum Pharmaceuticals Announces that the FDA is Deferring its Action on the BLA for ROLONTIS® (eflapregastim)

October 26, 2020

*Agency cites inability to conduct inspection of the drug substance manufacturing facility due to COVID-19 related travel restrictions*

HENDERSON, Nev.--(BUSINESS WIRE)--Oct. 26, 2020-- Spectrum Pharmaceuticals (NasdaqGS: SPPI), a biopharmaceutical company focused on novel and targeted oncology therapies, today announced that an inspection of the Hanmi Bioplant in South Korea is required before the FDA can approve the company's Biologics License Application (BLA) for ROLONTIS. The FDA was unable to conduct an inspection during the current review cycle due to restrictions on travel related to the COVID-19 pandemic. Therefore, the FDA is deferring action on the application until an inspection can be completed. The company will continue to work actively with the FDA to define an approach for scheduling the required inspection. Spectrum has confirmed with the FDA that this is not a Complete Response Letter.

"We are actively working with the FDA to find a way to expedite the plant inspection," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "The manufacturing facility is ready for inspection and we are eager to assist the FDA in completing their assessment as soon as possible."

### About ROLONTIS

ROLONTIS is a novel, long-acting granulocyte colony-stimulating factor (G-CSF) seeking an indication for the treatment of neutropenia in patients receiving myelosuppressive anti-cancer drugs. 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 chemotherapy. 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 trials.

### 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](http://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. Forward-looking statements include statements that are not purely statements of historical fact, and can generally be identified by our use of words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," "pipeline," "launch," and similar terms, or by express or implied discussions relating to Spectrum's business and its future, including the timing and outcome of the FDA's inspection of the Hanmi Bioplant in South Korea, the FDA's ability to complete the inspection using alternative means, the overall likelihood of success and timing of the company's BLA for ROLONTIS, the future potential of Spectrum's existing drug pipeline, including ROLONTIS, 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 Spectrum's existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, 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.*

SPECTRUM PHARMACEUTICALS, INC.® and ROLONTIS® are registered trademarks of Spectrum Pharmaceuticals, Inc. and its affiliate. REDEFINING CANCER CARE™ and the Spectrum Pharmaceuticals logos are trademarks owned by Spectrum Pharmaceuticals, Inc. Any other trademarks are the property of their respective owners.

© 2020 Spectrum Pharmaceuticals, Inc. All Rights Reserved

View source version on [businesswire.com](https://www.businesswire.com/news/home/20201026005289/en/): <https://www.businesswire.com/news/home/20201026005289/en/>

Robert Uhl  
Managing Director, Westwicke ICR  
858.356.5932  
[robert.uhl@westwicke.com](mailto:robert.uhl@westwicke.com)

Kurt Gustafson

Chief Financial Officer  
949.788.6700  
[InvestorRelations@sppirx.com](mailto:InvestorRelations@sppirx.com)

Source: Spectrum Pharmaceuticals