Verastem Oncology Announces Submission of a Marketing Authorization Application to the European Medicines Agency for COPIKTRA® (duvelisib)

November 25, 2019

BOSTON--(BUSINESS WIRE)--Nov. 25, 2019-- Verastem, Inc. (Nasdaq:VSTM) (Verastem Oncology or the Company), a biopharmaceutical company focused on developing and commercializing medicines seeking to improve the survival and quality of life of cancer patients, today announced the submission of a Marketing Authorization Application to the European Medicines Agency (EMA) for COPIKTRA® (duvelisib), an oral inhibitor of phosphoinositide 3-kinase (PI3K), seeking approval for the treatment of patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and relapsed or refractory follicular lymphoma (FL).

“We have seen the significant benefit of COPIKTRA as a treatment option for patients throughout our clinical trials and experience globally,” said Brian Stuglik, Chief Executive Officer of Verastem Oncology. “The MAA submission for COPIKTRA in Europe is an important milestone in our mission to offer new therapies to patients in need and we are committed to working effectively with the EMA through the regulatory process to bring COPIKTRA to patients in Europe.”

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a commercial biopharmaceutical company committed to the development and commercialization of medicines to improve the lives of patients diagnosed with cancer. We are driven by the strength, tenacity and courage of those battling cancer – single-minded in our resolve to deliver new therapies that not only keep cancer at bay, but improve the lives of patients diagnosed with cancer. Because for us, it’s personal.

Our first FDA approved product is now available for the treatment of patients with certain types of indolent non-Hodgkin’s lymphoma (iNHL). Our pipeline comprises product candidates that seek to treat cancer by modulating the local tumor microenvironment. For more information, please visit www.verastem.com.

Forward looking statements notice

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including those related to the safety and efficacy of COPIKTRA; whether and when the EMA may approve the Marketing Authorization for COPIKTRA, which will depend on the assessment by the EMA of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted, and if approved, whether COPIKTRA will be commercially successful in Europe; and that COPIKTRA will not result in new treatment options being offered to patients in Europe. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements.

Other risks and uncertainties include those identified under the heading “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019, as filed with the Securities and Exchange Commission (SEC) on October 30, 2019, its Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the SEC on March 12, 2019, and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology’s views as of the date hereof, and the Company does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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