



Verastem Oncology Announces COPIKTRA™ (Duvelisib) Presentations at the Lymphoma & Myeloma 2019 International Congress

October 23, 2019 at 7:00 AM EDT

BOSTON--(BUSINESS WIRE)--Oct. 23, 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 that five posters highlighting clinical data for COPIKTRA™ (duvelisib) will be presented at the Lymphoma & Myeloma 2019 International Congress taking place October 23-26, 2019, in New York City. The presented abstracts focus on clinical data from the Phase 3 DUO study, including evaluation of COPIKTRA efficacy and safety in high-risk patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), dose modification data and results from a post-hoc analysis evaluating the effect of COPIKTRA on lymphocytosis in patients. Other presented data include the characterization of duvelisib in patients with refractory Marginal Zone Lymphoma from the Phase 2 DYNAMO study, and an update on the safety profile and management of adverse events in heavily pre-treated patients with advanced hematological malignancies.

"Findings from the DUO study demonstrated that patients taking duvelisib who have received two or more prior therapies experienced improved clinical outcomes and a manageable safety profile," states Matthew S. Davids, MD, Associate Director, Center for Chronic Lymphocytic Leukemia at Dana-Farber Cancer Institute. "These results with duvelisib are important for this patient population, which is in need of targeted therapies to control their disease."

"The data presented at this year's Lymphoma & Myeloma Congress reflect the utility of duvelisib in patients with relapsed or refractory CLL/SLL after at least two prior therapies, including in patients with advanced disease or at high-risk of recurrence," commented Hagop Youssoufian, MSc, M.D., Head of Medical Strategy at Verastem Oncology. "Further, the research supports the approach to management of adverse events through dose interruptions or dose reductions without an impact on the patient's response, which could allow patients who are benefitting to stay on therapy longer."

COPIKTRA, a targeted oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, received approval as monotherapy from the U.S. Food and Drug Administration (FDA) in September 2018 for the treatment of patients with relapsed or refractory CLL/SLL after at least two prior therapies. COPIKTRA also received accelerated approval for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. Continued approval in FL may be contingent upon verification and description of clinical benefit in confirmatory trials.

Details for the poster presentations are as follows:

Title: An improved benefit-risk profile of duvelisib in patients with chronic lymphocytic leukemia or small lymphocytic lymphoma who received ≥ 2 prior therapies

Lead author: Matt Davids, M.D., Dana-Farber Cancer Institute, Boston, MA

Presentation ID: P-012

Title: Effect of dose modifications on response to duvelisib in patients with relapsed or refractory CLL/SLL in the DUO trial

Lead author: Nicole Lamanna, Columbia University Medical Center

Presentation ID: P-030

Title: Patterns of duvelisib-induced lymphocytosis in patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma, including those with high-risk factors treated in the DUO trial

Lead author: Jacqueline Barrientos, Zucker School of Medicine at Hofstra/Northwell

Presentation ID: P-015

Title: Characterization of duvelisib in patients with refractory marginal zone lymphoma: data from the phase 2 DYNAMO trial

Lead author: Eric Jacobsen, Dana-Farber Cancer Institute, Boston, MA

Presentation ID: P-029

Title: Safety Profile and Management of Adverse Events Associated with Duvelisib in Patients with Advanced Hematologic Malignancies

Lead author: Karen Francoeur, Verastem Oncology

Presentation ID: P-031

PDF copies of these poster presentations will be available [here](#) after the meeting.

COPIKTRA includes a Boxed Warning for fatal and serious toxicities including infections, diarrhea or colitis, cutaneous reactions and pneumonitis. See full [Prescribing Information](#) for complete Boxed Warning and other important safety information.

SELECT IMPORTANT SAFETY INFORMATION

This does not include all information needed to use COPIKTRA™ (duvelisib) safely and effectively. [See full Prescribing Information.](#)

WARNING: FATAL AND SERIOUS TOXICITIES: INFECTIONS, DIARRHEA OR COLITIS, CUTANEOUS REACTIONS, and PNEUMONITIS

See full Prescribing Information for complete boxed warning

- Fatal and/or serious infections occurred in 31% (4% fatal) of COPIKTRA-treated patients. Monitor for signs and symptoms of infection. Withhold COPIKTRA if infection is suspected.
- Fatal and/or serious diarrhea or colitis occurred in 18% (<1% fatal) of COPIKTRA-treated patients. Monitor for the development of severe diarrhea or colitis. Withhold COPIKTRA.
- Fatal and/or serious cutaneous reactions occurred in 5% (<1% fatal) of COPIKTRA-treated patients. Withhold COPIKTRA.
- Fatal and/or serious pneumonitis occurred in 5% (<1% fatal) of COPIKTRA-treated patients. Monitor for pulmonary symptoms and interstitial infiltrates. Withhold COPIKTRA.

INDICATIONS AND USAGE

COPIKTRA is a kinase inhibitor indicated for the treatment of adult patients with:

- Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.
- Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. Accelerated approval based on overall response rate and continued approval may be contingent upon confirmatory trials

WARNINGS AND PRECAUTIONS

- Hepatotoxicity: Monitor hepatic function.
- Neutropenia: Monitor blood counts.
- Embryo-Fetal toxicity: COPIKTRA can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) are diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, and anemia.

To report Adverse Reactions, contact FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch and Verastem Oncology at 1-877-7RXVSTM (1-877-779-8786).

DRUG INTERACTIONS

- CYP3A inducers: Avoid co-administration with strong CYP3A inducers.
- CYP3A inhibitors: Monitor for COPIKTRA toxicities when co-administered with strong or moderate CYP3A inhibitors. Reduce COPIKTRA dose to 15 mg twice daily when co-administered with strong CYP3A4 inhibitors.
- CYP3A substrates: Monitor for signs of toxicities when co-administering COPIKTRA with sensitive CYP3A substrates.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed.

About COPIKTRA™ (duvelisib)

COPIKTRA is an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, two enzymes known to help support the growth and survival of malignant B-cells. PI3K signaling may lead to the proliferation of malignant B-cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment.^{1,2,3} COPIKTRA is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. COPIKTRA is also being developed by Verastem Oncology for the treatment of peripheral T-cell lymphoma (PTCL), for which it has received Fast Track status and Orphan Drug Designation, and is being investigated in combination with other agents through investigator-sponsored studies.⁴ For more information on COPIKTRA, please visit www.COPIKTRA.com. Information about duvelisib clinical trials can be found on www.clinicaltrials.gov.

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; the uncertainties inherent in research and development of COPIKTRA, such as negative or unexpected results of clinical trials; that enrollment of clinical trials may take longer than expected; and that COPIKTRA or our other product candidates will cause unexpected safety events, experience manufacturing or supply interruptions or

failures, or result in unmanageable safety profiles as compared to their levels of efficacy. 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 June 30, 2019, as filed with the Securities and Exchange Commission (SEC) on August 1, 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.

References

¹ Winkler D.G., Faia K.L., DiNitto J.P. et al. PI3K-delta and PI3K-gamma inhibition by IPI-145 abrogates immune responses and suppresses activity in autoimmune and inflammatory disease models. *Chem Biol* 2013; 20:1-11.

² Reif K et al. Cutting Edge: Differential Roles for Phosphoinositide 3 kinases, p110-gamma and p110-delta, in lymphocyte chemotaxis and homing. *J Immunol* 2004;173:2236-2240.

³ Schmid M et al. Receptor Tyrosine Kinases and TLR/IL1Rs Unexpectedly activate myeloid cell PI3K, a single convergent point promoting tumor inflammation and progression. *Cancer Cell* 2011;19:715-727.

⁴ www.clinicaltrials.gov, NCT03372057.

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