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Verastem's Copiktra gets U.S. FDA nod

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Approval for Clopiktra was based on positive Phase III trial results that showed the medication demonstrated a superior progression-free survival over ofatumumab (Novartis' Arzerra), a standard of care treatment for CLL.

Verastem, Inc. focused on developing and commercializing medicines to improve the survival and quality of life of cancer patients has announced that the U.S. Food and Drug Administration (FDA) has approved COPIKTRA, an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma. COPIKTRA is approved for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (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. The indication in FL is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

"With today's FDA approval of COPIKTRA, Verastem Oncology is delivering upon our commitment to patients with cancer by bringing a new oral medicine to market," said Robert Forrester, President and Chief Executive Officer of Verastem Oncology. "We are pleased to be able to introduce COPIKTRA during National Blood Cancer Awareness Month. At Verastem Oncology, we are driven by the strength and courage of those battling cancer, and we are committed to advancing therapies such as COPIKTRA with the potential to make a significant impact for patients, their caregivers and physicians. We are immensely grateful to the many patients who participated in the duvelisib clinical trial program over the years leading to this pivotal moment."

"COPIKTRA is an important addition to the evolving treatment paradigm for patients with CLL/SLL and FL," said Ian Flinn, MD, PhD, Director of the Lymphoma Research Program at Sarah Cannon Research Institute and lead investigator of the DYNAMO™ and DUO™ studies. "The approval of COPIKTRA for the treatment of relapsed or refractory CLL/SLL after at

least two prior therapies, or relapsed or refractory FL after at least two prior systemic therapies, is based on clinical trial data gathered from the treatment of over 400 adult patients. COPIKTRA is a significant addition to physicians' treatment armamentarium that I believe will address an unmet need for patients who have limited options once they have progressed after two prior therapies."

Lymphoma is the most common blood cancer, and CLL/SLL and FL are common types of indolent non-Hodgkin lymphomas (iNHL). There are an estimated 681,000 people living with non-Hodgkin lymphoma in the US alone, including nearly 350,000 cases of CLL/SLL or FL. Many of these patients will eventually relapse or develop refractory disease.

"Each lymphoma patient's experience is unique, and today's approval offers patients with CLL/SLL and FL a new treatment option and a new opportunity for hope," said Meghan Gutierrez, Chief Executive Officer of the Lymphoma Research Foundation. "We applaud the FDA, Verastem and the patients who participated in the clinical trials for their roles in advancing treatment options for people living with CLL/SLL and FL."

The New Drug Application for COPIKTRA received Priority Review. Priority Review is reserved for medicines that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The FDA had previously granted COPIKTRA Fast Track Designation in CLL and FL as well as Orphan Drug Designation for CLL/SLL and FL. For the indication of FL, COPIKTRA was approved under FDA regulations for accelerated approval.

"We are excited to offer a new treatment that can allow patients to manage their disease with an oral monotherapy," said Joseph Lobacki, Executive Vice President and Chief Commercial Officer of Verastem Oncology. "We continue to hear from physicians and patients that there is a great need for additional treatment options to fight chronic cancers such as CLL/SLL and FL. In preparation for this approval, we have assembled an experienced oncology commercial team, established our distribution network, and we are ready to make COPIKTRA commercially available to patients."

COPIKTRA will be available in the U.S. market immediately. Verastem Oncology is committed to helping patients with CLL/SLL and FL access COPIKTRA through our Verastem Cares program. Verastem Cares is a comprehensive, personalized program designed to provide information and assistance to patients who have been prescribed COPIKTRA.