

Risk Evaluation and Mitigation Strategy (REMS) Document

COPIKTRA™ (duvelisib) REMS Program

I. Administrative Information

Application Number: NDA 211155

Application Holder: Verastem, Inc.

Initial REMS Approval: 9/2018

II. REMS Goal

The goal of the COPIKTRA REMS is to mitigate the risks of fatal and/or serious toxicities including infections, diarrhea or colitis, cutaneous reactions, and pneumonitis associated with the use of COPIKTRA by informing healthcare providers of these risks.

III. REMS Requirements

To inform healthcare providers about the REMS Program and the risks and safe use of COPIKTRA, Verastem, Inc. must disseminate REMS communication materials according to the table below:

| Target Audience | Communication Materials & Dissemination Plans |
|--|---|
| <p>Healthcare providers who are likely to prescribe COPIKTRA</p> | <p>REMS Letters: Healthcare Provider REMS Letter, Professional Society REMS Letter with hyperlink to the Fact Sheet</p> <ol style="list-style-type: none"> 1. E-mail within 60 calendar days of the date COPIKTRA is first commercially distributed and again 12 months later. <ol style="list-style-type: none"> a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 2. Make available via a link from the COPIKTRA REMS Program Website. 3. Disseminate through field-based sales and medical representatives for 1 year from the date COPIKTRA is first commercially distributed. 4. Disseminate within 60 calendar days of the date COPIKTRA is first commercially distributed and again 12 months later through the following professional societies and request the letter or content be provided to their members. <ol style="list-style-type: none"> a. American Society of Clinical Oncology (ASCO); American Society of Hematology (ASH); Oncology Nursing Society (ONS); National Comprehensive Cancer Network (NCCN); Hematology Oncology Pharmacy Association (HOPA); American Pharmacists Association (APhA); American Society of Health-System Pharmacists (ASHP) 5. Disseminate at Professional Meetings where Verastem has a presence for 1 year from the date COPIKTRA is first commercially distributed. <p>Fact Sheet</p> <ol style="list-style-type: none"> 1. Disseminate and prominently display at Professional Meetings where Verastem has a presence for 1 year from the date COPIKTRA is first commercially distributed. 2. Disseminate through field-based sales and medical representatives during the initial and/or follow-up discussion with healthcare providers for 1 year after COPIKTRA is first commercially distributed. Field-based sales and medical representatives to orally review the risk messages contained in the Fact Sheet during the visit with the healthcare provider. <p>Patient Safety Wallet Card</p> <ol style="list-style-type: none"> 1. Disseminate through field-based sales and medical representatives to healthcare providers for 1 year from the date COPIKTRA is first commercially distributed. <p>Website</p> <ol style="list-style-type: none"> 1. Make the REMS Program website fully operational and all REMS materials available through the website by the date COPIKTRA is first commercially distributed. 2. Include a prominent REMS-specific link to the COPIKTRA REMS Program website on all product websites for consumers and healthcare providers. |

| Target Audience | Communication Materials & Dissemination Plans |
|-----------------|---|
| | <p>The COPIKTRA REMS Program website must not link back to the promotional product website(s).</p> <p>3. Continue for as long as the COPIKTRA REMS is active.</p> |

IV. REMS Assessment Timetable

Verastem, Inc. must submit REMS Assessments at 18 months, 3 years and 7 years from the date of initial REMS approval (09/24/2018). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Verastem, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the COPIKTRA REMS:

Communication Materials

1. [Healthcare Provider REMS letter](#)
2. [Professional Society REMS letter](#)
3. [Fact Sheet](#)
4. [Patient Safety Wallet Card](#)

Other Materials

5. [COPIKTRA REMS Program website](#)