Copiktra™
(duvelisib)

FDA-REQUIRED REMS SAFETY INFORMATION

COPIKTRA has the following risks of fatal and/or serious toxicities:
- **Infections**
- **Diarrhea or Colitis**
- **Cutaneous Reactions**
- **Pneumonitis**

Dear **<PROFESSIONAL SOCIETY NAME>**:

The Food and Drug Administration (FDA) has required this safety notice as part of the COPIKTRA REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of COPIKTRA.

We would like to ask you to please distribute this information to your members so they are aware of the following risks.

Serious Risks with Use of COPIKTRA

COPIKTRA can cause fatal and/or serious toxicities including **infections, diarrhea or colitis, cutaneous reactions, and pneumonitis**.

Enclosed are the following materials:

- COPIKTRA Fact Sheet
- COPIKTRA Prescribing Information
- COPIKTRA Patient Safety Wallet Card

Please encourage your members to provide the Patient Safety Wallet Card to all patients being treated with COPIKTRA. The Patient Safety Wallet Card, Fact Sheet, and other important information are available at: www.COPIKTRAREMS.com.

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.
  This indication 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.

Sincerely,

Verastem Oncology

Verastem Oncology

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