Copiktra®
(duvelisib) 15mg | 25mg capsules

FDA-Required REMS Safety Information
Important Update: Treatment-related Mortality

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 following update to the Prescribing Information in July 2024.

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

Treatment-related Mortality

In a randomized controlled study in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), treatment with COPIKTRA was associated with increased treatment-related mortality. With an extended follow-up period, median of 63 months, fatal adverse reactions occurred in 15% of patients treated with COPIKTRA and in 3% of patients treated in the comparator arm.

Advise patients that COPIKTRA has been associated with increased deaths due to side effects of therapy in a randomized study when compared to standard therapy. The main reason for death was infection.

Serious Toxicities

In addition, 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

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 CLL or SLL after at least two prior lines of systemic therapy.

Limitations of Use

COPIKTRA is not indicated or recommended for the treatment of any patients with CLL or SLL as initial or second line treatment due to an increased risk of treatment-related mortality.

Sincerely,
Secura Bio, Inc.

SecuraBio

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