

NDA 205353 FARYDAK (panobinostat)

histone deacetylase inhibitor

Secura Bio, Inc.

1995 Village Center Cir, Suite 128

Las Vegas, NV 89134-6360

Phone: 844-973-2872

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. Goal(s)

The goal of the FARYDAK REMS is to mitigate the risks of severe diarrhea and cardiac toxicities (severe and fatal cardiac ischemic events, severe arrhythmias, and ECG changes) associated with FARYDAK treatment

- by informing healthcare providers about the risks of severe diarrhea and cardiac toxicities associated with FARYDAK

II. REMS elements

Communication Plan

Secura Bio will implement the following communication plan for healthcare providers who are likely to prescribe and dispense FARYDAK. This communication plan will include:

1. REMS Letters

Secura Bio will send *REMS Letter to Healthcare Providers* and *REMS Letter for Professional Societies* within 30 days of REMS approval (02/23/2015). Secura Bio will send a second emailing 12 months from the date of the REMS approval. The REMS Letters will address the risks of severe diarrhea and severe and fatal cardiac toxicities associated with FARYDAK. Email will be used as the primary method to disseminate the REMS Letters. If email is marked unopened, a second email will be sent within 30 calendar days of the date the first email was sent. If the second email is marked unopened, the REMS Letters will be mailed within 30 calendar days of the date of the second email was sent. If a healthcare provider's or professional society's email address is not available, or if an email is undeliverable, the REMS Letter will be mailed within 30 calendar days of the date of the bulk mailing. A copy or link to the Prescribing Information (PI) and *REMS Factsheet* will accompany each *REMS Letter for Healthcare Providers*. A copy or link to the *REMS Factsheet* will accompany each *REMS Letter for Professional Societies*.

a. REMS Letter for Healthcare Providers

The intended audience for the *REMS Letter for Healthcare Providers* will be oncologists, oncology physician assistants, oncology nurse practitioners, hematologists, oncology nurses, and pharmacists.

b. REMS Letter for Professional Societies

The intended audience for the *REMS Letter for Professional Societies* will be the following professional societies and organizations, in which Secura Bio requests the letter or content be

provided to their membership:

- 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)

2. REMS Factsheet

A *REMS Factsheet* will be made available for healthcare providers and disseminated through Secura Bio field-based sales or medical representatives during the initial discussion with healthcare providers within the first 12 months after the approval of this REMS. Secura Bio field-based sales or medical representatives will orally discuss the risk messages contained in the *Factsheet* during the visit with the healthcare provider.

3. Journal Information Piece

Secura Bio will publish in the following professional journals an *information piece* that includes the risks of serious and severe diarrhea associated with FARYDAK treatment.

- Journal of Clinical Oncology
- Blood
- New England Journal of Medicine
- Hematology Oncology Today
- Oncology & Hematology Review
- Leukemia and Lymphoma

The *information piece* will be published quarterly in each publication for one year following the REMS approval.

4. Scientific Meetings

FARYDAK REMS materials will be prominently displayed and disseminated at relevant scientific meetings where Secura Bio has a presence (e.g., booth) for the duration of the REMS.

5. REMS Program Website

The FARYDAK *REMS Website* (www.FARYDAK-REMS.com) will continue for the duration of the REMS. The REMS program website will include the option to print the PI, Medication Guide, REMS Letters, and *REMS Factsheet*. The FARYDAK product website will include a prominent REMS-specific link to the *FARYDAK REMS Program Website*.

The following are part of the REMS and are appended:

- REMS Letter to Healthcare Providers (print and email versions)
- REMS Letter for Professional Societies (print and email versions)
- REMS Factsheet
- The Journal Information Piece
- FARYDAK REMS Website Landing Page

III. Timetable for Submission of Assessments

Secura Bio will submit REMS assessments to FDA 18 months, 3 years and 7 years from the date of the initial approval of the REMS [02/23/2015]. 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 days before the submission date for each assessment time interval. Secura Bio will submit each assessment so that it will be received by FDA on or before the due date.