Errata to FDA Briefing Document

Oncologic Drugs Advisory Committee Meeting
December 18, 2019

NDA 211723
Tazemetostat
Applicant: Epizyme

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ODAC Meeting
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This document contains errata to the original FDA Briefing Document. The erroneous text is followed by the correction in bold below.

1. Page 7, Section 2.1 Major Issue for Discussion at ODAC, text below:

   In the pooled safety population of 725 adults and pediatric patients with solid tumors or hematologic malignancies, 6 (0.8%) patients developed secondary myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), or T-cell lymphoblastic lymphoma (T-LBL).

   Corrected to read as:

   In the pooled safety population of 725 adults and **97** pediatric patients with solid tumors or hematologic malignancies, 6 **(0.7%)** patients developed secondary myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), or T-cell lymphoblastic lymphoma (T-LBL).

2. Page 9, Table 2 Key Regulatory Activities, Row 3, text below:

   11/23/2015 IND submitted.

   Corrected to read as:

   7/23/2015 IND submitted.

3. Page 25, Section 4.2.3.6 Analysis of Secondary Malignancies, text below:

   Across the overall development program, 6 (0.8%) of 725 patients developed a secondary malignancy as of May 24, 2019.

   Corrected to read as:

   Across the overall development program, 6 **(0.7%)** of **822** patients developed a secondary malignancy as of May 24, 2019.