Errata to the FDA Briefing Document

Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee Meeting (ODAC)

June 22, 2017

Prexasertib

Applicant: Eli Lilly and Company
Page 13, 1st paragraph, 2nd sentence

Forty-five to Sixty-three patients were enrolled in the dose escalation portion of the trial starting at a dose of 10 mg/m² on days 1 to 3 and 3 of a 14-day cycle or 40 mg/m² on day 1 of a 14 day cycle and established the maximum tolerated doses (MTDs) of 40 mg/m² on days 1 to 3 and 3 of a 14 day cycle and 105 mg/m² on day 1 of a 14 day cycle.”

Page 13, 1st paragraph, 4th sentence

In the dose escalation dose expansion, cohort 43 patients were evaluable for response and two patients (4.6%) had a partial response (PR) ……”

Page 13, 1st paragraph, last sentence

Given the safety, efficacy, predicted target inhibition and PK/PD data obtained during the dose-escalation portion of the study the recommended phase 2 dose (RP2D) was determined to be 105 mg/m² on day 1 of a 14-day cycle.”

Page 13, 2nd paragraph, 1st sentence

In the expansion cohorts of Trial JTJA, 83 patients were treated, 57 patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and 26 with metastatic or recurrent squamous cell carcinoma (SCC) of the anus.

Page 13, 3rd paragraph, 2nd sentence

Prexasertib has been evaluated in a panel of pediatric tumor cell lines, in more than 25 mouse xenograft models of pediatric or adolescent/young adult tumors, and in the National Cancer Institute’s (NCI) pediatric preclinical testing program (PPTP) and pediatric preclinical testing consortium (PPTC).

Page 14, 1st paragraph, 2nd sentence

In these evaluations, prexasertib demonstrated in vitro inhibition across multiple cell lines with the most sensitive cell line being MYCN-amplified neuroblastoma.”

Page 14, 2nd paragraph, last sentence

Lilly hypothesizes that tumors with MYCN amplification will have increased sensitivity to a CHK1 inhibitor such as prexasertib.

Page 14, 3rd paragraph, 2nd sentence

Additionally, translocation t(2;3) and t(1;13) resulting in PAX3/FOXO1 and PAX7/FOXO1 fusion genes occur in 80% of alveolar rhabdomyosarcoma and correlate with MYCN amplification in 25% of cases or MYCN overexpression in 55% of cases 80% of cases.”