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

Errata to the FDA Briefing Document for Prexasertib
ODAC Meeting

Page 13, 1st paragraph, 2nd sentence

Forty-five ~~Sixty-three~~ patients were enrolled in the dose escalation portion of the trial starting at a dose of 10 mg/m^2 on days **1 to 3** ~~1 and 3~~ of a 14-day cycle or 40 mg/m^2 on day 1 of a 14 day cycle and established the maximum tolerated doses (MTDs) of 40 mg/m^2 on days **1 to 3** ~~1 and 3~~ of a 14 day cycle and 105 mg/m^2 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** ~~predict~~ 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** ~~ands~~ 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** ~~xenograph~~ 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** ~~evaluation~~, 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** ~~hypothesize~~ that tumors with MYCN amplification will have increased sensitivity to a CHKl inhibitor such as prexasertib.

Page 14, 3rd paragraph, 2nd sentence

Additionally, translocation t(2;3) and t(1:13) resulting in P AX3/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~~."