Errata to FDA Briefing Document

Oncologic Drugs Advisory Committee

July 13, 2017

BLA 761028

ABP215, a proposed biosimilar to Avastin (bevacizumab)

Amgen Inc.

DISCLAIMER STATEMENT

The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package often contains assessments and/or conclusions and recommendations written by individual FDA reviewers. Such conclusions and recommendations do not necessarily represent the final position of the individual reviewers, nor do they necessarily represent the final position of the Review Division or Office. We bring the 351(k) BLA for ABP215 with the Applicant's proposed indications to this Advisory Committee to gain the Committee's insights and opinions. The background package may not include all issues relevant to the final regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the Advisory Committee. The FDA will not issue a final determination on the issues at hand until input from the Advisory Committee process has been considered and all reviews have been finalized. The final determination may be affected by issues not discussed at the Advisory Committee meeting.

Errata to the FDA Briefing Document
ODAC Meeting
July 13, 2017

The document is an errata to the Clinical Outcomes section (Section 10) of the original FDA briefing document. The erroneous text is identified by a strikethrough with correction in bold below.

Page 49, Section 10.2 Study Results

The ORR is 48% in both arms with a risk ratio of **1.01** ~~1.1~~ (90% CI 0.88; 1.16).