FDA Briefing Document

Second Addendum

BLA 761176

Drug name: ^{131}I-omburtamab

Applicant: Y-mAbs Therapeutics, Incorporated

Oncologic Drugs Advisory Committee Meeting

October 28, 2022

Division of Oncology 2/Office of Oncologic Diseases

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 have brought the assessment of the evidence of effectiveness for ^{131}I-omburtamab to this Advisory Committee in order to gain the Committee's insights and opinions, and 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.

FDA is amending the briefing document to add the underlined phrase to the following sentence, which appears as the last sentence on p.20 and on the last row of Table 3 (bottom of p.23) in the briefing document.

> *On March 31, 2022, Y-mAbs elected to resubmit the BLA prior to reaching agreement with the FDA on the content of the application <u>with respect to the plan for audit of the external control data and information submitted regarding the type and dose of CNS-directed radiation therapy</u>.*