

Oncologic Drugs Advisory Committee (ODAC) Meeting

[April 29, 2021]

NDA/BLA# 125554/S-041

Drug name: nivolumab

Applicant: Bristol Myers Squibb

ERRATA

To the Combined FDA and Applicant ODAC Briefing Document

Errata to the Briefing Document:

1. On page 15: “As stated above by the Applicant, based on data from a registry, professional associations recommend expansion of the use of sorafenib to patients with Child-Pugh B~~6-7~~ cirrhosis”. Revision to delete ‘6’ in front of Child-Pugh B.
2. On page 26: “Nearly all patients had a Child-Pugh ~~B~~ score of 5 or 6 and most (89%) were BCLC Stage C. Black patients were underrepresented in the trial compared to the US population.” Revision to delete ‘B’ in front of Child-Pugh.
3. On page 39: “In addition, the study’s final ~~survival~~ analysis for TTTP is estimated to be conducted in 2026.” Revision to delete ‘survival’ and include ‘for TTTP’ based on BMS’s . clarification regarding Table 5.2-1.