

Errata to FDA Briefing Document
Oncologic Drugs Advisory Committee Meeting
February 9, 2023

This errata contains corrections to FDA’s Briefing Document.

| Page | Action |
|------|--|
| 5 | Replace redacted text with “perioperative” |
| 6 | Replace redacted text with “perioperative” |
| 7 | Redact |
| 10 | Replace redacted text with “2” |
| 12 | Replace redacted text with “1” |
| 16 | Replace with “Available data suggests that an 2.75-21% of cases rectal cancer are dMMR/MSI-H, with prevalence decreasing for more advanced disease stage. (Bonneville R, 2017; Swets M, 2022; Papke D, 2022; Lorenzi M, 2020).” |
| 17 | Add at the end of sentence references “(Yuki S, 2020; Lin Z, 2021; Salvatore L, 2021)” |
| 20 | Redact |
| | Replace redacted text with “219369” |
| 21 | Replace redacted text with “219369” |
| 23 | Replace redacted text with “219369” |
| 25 | Replace redacted text with for “perioperative” |
| | Replace redacted text with for “perioperative” |
| 26 | Replace redacted text with for “perioperative” |
| 28 | <p>Add references:</p> <p>Yuki S, Bando H, Tsukada Y, Inamori K, Komatsu Y et al. Short-term results of VOLTAGE-A: Nivolumab monotherapy and subsequent radical surgery following preoperative chemoradiotherapy in patients with microsatellite stability and microsatellite instability-high, locally advanced rectal cancer (EPOC 1504). <i>Annals of Oncology</i> V31 S3 S230-S231, 2020</p> <p>Lin Z,Cai M, Zhang P,Gang L, Liu T et al. Phase II, single-arm trial of preoperative short-course radiotherapy followed by chemotherapy and camrelizumab in locally advanced rectal cancer. <i>J Immunother</i> 2021 Nov;9(11):e003554</p> <p>Salvatore L, Bensi M, Corallo S, et al: Phase II study of preoperative chemoradiotherapy plus avelumab in patients with locally advanced rectal cancer: The AVANA Study. <i>ESMO World Gastrointestinal Cancer Congress 2021. Abstract O-12.</i></p> |