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NCCN Guidelines® Panel: Gastric Cancer Panel

Dear Panel Members:

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO® (nivolumab) clinical data that was recently presented at the European Society for Medical Oncology (ESMO) 2017 Annual Meeting for the Panel's consideration. Please find the following data enclosed:

- Interim safety and clinical activity from ATTRACTION-04 (ONO-4538-37), a phase 2/3 study which evaluated the use of nivolumab in combination with S-1/capecitabine plus oxaliplatin in patients with previously untreated unresectable advanced or recurrent gastric/gastroesophageal junction cancer.¹
- Updated results from ATTRACTION-02 (ONO-4538-12), a phase 3 study of nivolumab monotherapy in previously treated advanced gastric or gastroesophageal junction cancer.²

The use of nivolumab for the treatment of advanced gastric and gastroesophageal junction is considered investigational.³

Rationale: These data are submitted in response to a standing request from NCCN for new clinical data. Original presentation of data from the phase 3 study, ATTRACTION-02 (ONO-4538-12), was previously submitted to the panel on March 8, 2017, reflecting the safety and efficacy of nivolumab compared to placebo as a treatment option for patients with third or later line advanced gastric or gastroesophageal junction cancer.

The following resources are included for your review:

1. Kang YK, Kato K, Chung HC et al. Interim Safety and Clinical Activity of Nivolumab in Combination With S-1/Capecitabine Plus Oxaliplatin in Patients With Previously Untreated Unresectable Advanced or Recurrent Gastric/Gastroesophageal Junction Cancer: Part 1 Study of ATTRACTION-04 (ONO-4538-37). Poster presented at: European Society for Medical Oncology (ESMO) Congress; September 8-12, 2017; Madrid, Spain
2. Boku N, Kang YK, Satoh T et al. A Phase III Study of Nivolumab in Previously Treated Advanced Gastric or Gastroesophageal Junction Cancer: Updated Results and Subset Analysis by PD-L1 Expression (ATTRACTION-02). Oral Presentation at: European Society for Medical Oncology (ESMO) Congress; September 8-12, 2017; Madrid, Spain
3. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. July 2017.

Thank you for your consideration of this request.

Sincerely,

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