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REMEMBER TO CHANGE EMAIL SUBJECT LINE TO: Submission Request

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Date of request: February 26, 2016
NCCN Guidelines Panel: Non-Hodgkin's Lymphoma

On behalf of Genentech, Inc., I respectfully request the NCCN Non-Hodgkin's Lymphomas (NHL) Guideline Panel to review the updated Gazyva® (obinutuzumab) prescribing information, which includes a new FDA-approved indication for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.

Specific Changes:

Please consider the overall survival results for the follicular lymphoma patient population from the GADOLIN study and the following new FDA-approved indication for Gazyva:

Gazyva is indicated in combination with bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.

Currently, Gazyva is included as a maintenance therapy option for follicular lymphoma within the NCCN guidelines. Please consider Gazyva plus bendamustine as a treatment option in the induction portion of the treatment arm.

FDA Clearance:

- Gazyva was FDA-approved for the treatment of relapsed or refractory follicular lymphoma on February 26, 2016.

Please refer to the full prescribing information for FDA-approved indications and safety information.

- Full Gazyva® prescribing information available at: http://www.gene.com/download/pdf/gazyva_prescribing.pdf

Rationale:

- The FDA approval of Gazyva plus bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen is based on results from the pivotal Phase III study GADOLIN.
- The results from the GADOLIN study for the intent-to-treat population were previously submitted.[1]
- Additional survival results for the follicular lymphoma patient population described in the prescribing information are as follows:
    - Results showed that median progression-free survival (PFS) as assessed by an independent review committee (IRC), the primary endpoint, was 13.8 months in the bendamustine arm and was not reached in the Gazyva + bendamustine arm (HR 0.48, 95% CI, 0.34-0.68; p<0.0001). Investigator assessed PFS, a secondary endpoint, was 13.7 months for the bendamustine arm and 29.2 months in the Gazyva + bendamustine arm (HR 0.48, 95% CI, 0.35-0.67; p<0.0001).

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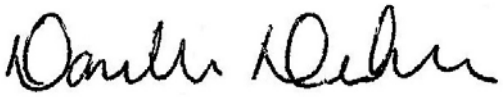
- The most common Grade 3/4 adverse reactions ≥ 10% of patients in the Gazyva-containing arm were neutropenia, thrombocytopenia, and infusion reactions.
- Because the trial did not randomize after induction to isolate the effect of maintenance alone, the best ORR, PFS and OS data were derived from patients who underwent the entire treatment regimen (Gazyva + bendamustine followed by Gazyva monotherapy). On trial, patients who progressed at any point in the regimen discontinued treatment.

Respectfully submitted,



Danielle Dishmon, Pharm.D.

Supplemental Reference

1. Sehn LH, Chua N, Mayer J, et al. GADOLIN: primary results from a Phase III study of obinutuzumab plus bendamustine compared with bendamustine alone in patients with rituximab-refractory indolent non-hodgkin lymphoma. Presented at the American Society of Clinical Oncology 2015 Annual Meeting in Chicago, IL; 2015 May 29 - June 2. ASCO Oral presentation.

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