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NCCN Guidelines® Panel: Chronic Myeloid Leukemia

Dear Panel Members:

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed Sprycel® (dasatinib) clinical data that has been recently presented at the American Society for Hematology (ASH) 2017 Annual Meeting to the NCCN Chronic Myeloid Leukemia Panel for review. This phase 2, open-label, single arm study evaluated treatment-free remission in adult patients with chronic myeloid leukemia in chronic phase (CML-CP) following the discontinuation of dasatinib, used as first-line therapy and beyond, in patients who achieved deep molecular response (DMR) for more than one year.¹

In addition, I also respectfully submit the enclosed Sprycel® (dasatinib) clinical data that was presented at the European Hematology Association (EHA) 2017 Annual Meeting for review. This data includes results from the 3 year follow-up of a phase 2, open-label, single arm study in Japan which evaluated whether second-line or subsequent dasatinib treatment after imatinib could be discontinued for a follow-up period longer than 12 months without relapse in patients with Philadelphia chromosome-positive (Ph+) CML-CP who maintained DMR for more than a year.²

FDA Clearance: The FDA approved Sprycel® (dasatinib) for the treatment of:³

- newly diagnosed adults with Ph+ CML-CP
- adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance (R/I) to prior therapy including imatinib
- pediatric patients with Ph+ CML-CP

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data.

The following resources are included for your review:

1. Shah N, Garcia Gutierrez JV, Jimenez A, et al. Dasatinib discontinuation in patients with chronic-phase chronic myeloid leukemia (CML-CP) and stable deep molecular response (DASFREE). Oral presentation presented at: The 59th American Society of Hematology Meeting; December 9-12, 2017; Atlanta, GA.
2. Nakamae H, Imagawa J, Tanaka H, et al. Final study results of discontinuation of dasatinib in patients with CML who maintained deep molecular response for longer than one year (DADI trial) after three years of follow-up. Poster presented at: The 22nd European Hematology Association Meeting; June 22-25, 2017; Madrid, Spain.
3. Sprycel® [package insert]. Princeton, NJ. Bristol-Myers Squibb Company. November 2017.



Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink that reads "Awny Farajallah". The signature is fluid and cursive, with a long horizontal stroke at the end.

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