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.  

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.  

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

Thank you for your consideration of this request.

Sincerely,

Awny Farajallah, MD, FACP
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