Dear NCCN Myeloproliferative Neoplasms Guidelines Panel Members:

On behalf of Celgene Corporation, we respectfully request that the NCCN Guidelines Panel for Myeloproliferative Neoplasms (MPNs) review the enclosed data and Prescribing Information for INREBIC® (fedratinib).

Specific Changes:

Please include fedratinib in the Clinical Guidelines for MPNs commensurate with publicly available data and the previous submission made by Celgene Corporation on June 27, 2019 (enclosed).

FDA Clearance:

On August 16, 2019 the US Food and Drug Administration (FDA) granted approval of INREBIC® (fedratinib) for the treatment of patients with myelofibrosis. The indication is as follows:

INREBIC® is indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).1

Please note the Boxed WARNING for Encephalopathy, including Wernicke’s: Serious and fatal encephalopathy, including Wernicke’s, has occurred in patients treated with INREBIC. Wernicke’s encephalopathy is a neurologic emergency. Assess thiamine levels in all patients prior to starting INREBIC, periodically during treatment, and as clinically indicated. Do not start INREBIC in patients with thiamine deficiency; replete thiamine prior to treatment initiation. If encephalopathy is suspected, immediately discontinue INREBIC and initiate parenteral thiamine. Monitor until symptoms resolve or improve and thiamine levels normalize.

Please see the enclosed full Prescribing Information.

Rationale for Proposed Change:

These data are being submitted as follow-up to the prior submission made to the panel on June 27, 2019 (enclosed).2

Your consideration of this submission is greatly appreciated.
Sincerely,

Albert Kodersha, PharmD
Senior Manager, Global Medical Information

Chrystal U Louis, MD, MPH
Executive Director, US Medical Affairs, Myeloid

REFERENCES

1. Celgene Corporation. Inrebic (fedratinib) [Package Insert]. Summit, NJ: Celgene Corporation
   https://media.celgene.com/content/uploads/inrebic-pi.pdf
2. Celgene Corporation. NCCN MPN Guidelines Submission; June 27, 2019