December 5, 2016

Submission Request
National Comprehensive Cancer Network® (NCCN®)

RE: Clinical Evidence in Support of ZYKADIA® (ceritinib*)* in ROS1 rearrangement positive Non-small Cell Lung Cancer

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Date of request:	December 5, 2016
NCCN Guidelines Panel:	Non-small Cell Lung Cancer (NSCLC)

To Whom It May Concern:

As the NCCN NSCLC Panel reviews the Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-small Cell Lung Cancer version 3.2017 and the associated Drugs and Biologics Compendium™, we have enclosed data relating to treatment with ceritinib. This information is highlighted below:

- Data to support the use of ceritinib in patients with ROS1 rearrangement positive NSCLC

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Ceritinib for ROS1 rearranged NSCLC
This request is for the Panel to consider including ceritinib as a treatment option in patients who are ROS1 rearrangement positive and update the target profile in the discussion to include ROS1 for ceritinib.

A Phase II Korean Nationwide, open-label, single-arm study of ceritinib 750 mg/day in patients (N=32) with ROS1 rearrangement positive NSCLC demonstrated an overall response rate of 62%. The most common AEs (any-grade) were diarrhea (78%), nausea (63%) and anorexia (59%). Most drug-related AEs were grade 1/2.[1]

Specific changes recommended for the Guidelines and Compendium
Please consider modifying sections NSCL-22 and relevant discussion and reference, of the NCCN Guidelines® for NSCLC to include ceritinib as a treatment option for ROS1 rearrangement positive NSCLC.

FDA status
Ceritinib is not FDA approved for the treatment of ROS1 rearrangement positive NSCLC.

Rationale for recommended change
The results of this study demonstrate the safety and efficacy of ceritinib in patients with ROS1 rearrangement positive NSCLC.[1]

Literature support

1. Lim SM, Kim HR, Lee JS, et al. Ceritinib in ROS1-rearranged non-small-cell lung cancer: a Korean nationwide phase II study (NCT01964157). Poster presented at: European Society for Medical Oncology; October 7 - October 11, 2016; Copenhagen, Denmark. Poster 1911.

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We appreciate the opportunity to provide this additional information for consideration by the NCCN NSCLC Panel. If you have any questions or require additional information, please do not hesitate to contact me at 862-778-5494 or via e-mail at neilda.baron@novartis.com. Thank you for your time and consideration.

Sincerely,

Neilda Baron, MD
Executive Director and Head, US Oncology Medical Information
Novartis Pharmaceuticals Corporation

Enclosures: Copy of referenced publication and ZYKADIA Prescribing Information
Disclosure: This study was sponsored by Yonsei University