June 1, 2017

Submission Request
National Comprehensive Cancer Network®

RE: Clinical Evidence in Support of Zykdia® (ceritinib) in ROS1 Rearrangement Positive Non-Small Cell Lung Cancer

Name: Neilda Baron, MD
Company/Organization: Novartis Pharmaceuticals Corporation
Address: One Health Plaza, Building 345
East Hanover, NJ 07936
Phone: 1-862-778-5494
E-mail: neilda.baron@novartis.com
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NCCN Guidelines Panel: Non-Small Cell Lung Cancer

To Whom It May Concern:

As an addendum to the submission to the NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®) for non-small cell lung cancer (NSCLC) and the associated Drugs & Biologics Compendium™ dated December 5, 2016, we are enclosing more recent published data in support of the use of ceritinib in ROS1 rearrangement positive NSCLC.

Specific changes recommended for the Guidelines and Compendium

This request is for the Panel to consider the addition of ceritinib as a treatment option in patients who are ROS1 rearrangement positive and update the target profile in section MS14 and MS28 to include ceritinib inhibits ALK, ROS1 and IGR1 receptors.

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 adverse events (AEs; any-grade) were diarrhea (78%), nausea (59%) and anorexia (56%). Most drug-related AEs were grade 1/2.1

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FDA status

Ceritinib is not FDA approved for the treatment of ROS1 rearrangement positive NSCLC. Ceritinib is a kinase inhibitor indicated for the treatment of patients with ALK+ metastatic NSCLC as detected by an FDA approved test.

Literature support

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 1-862-778-5494 or via e-mail at neilda.baron@novartis.com.

Thank you for your time and consideration.

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Sincerely,

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

Enclosures: Copy of Prescribing Information and referenced primary literature; author disclosures contained within reference