July 19, 2017

Submission Request
National Comprehensive Cancer Network® (NCCN®)

RE: Evidence in Support of Stomatitis Safety Profile With Afinitor® (everolimus) in Metastatic HR+/HER2- Breast Cancer

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Date of request: July 19, 2017
NCCN Guidelines Panel: Breast Cancer

To Whom It May Concern:

As an addendum to the submission to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer and the associated Evidence Blocks™ dated June 20, 2016, we are enclosing the following published article in support of the stomatitis safety profile with everolimus when used concomitantly with dexamethasone oral solution for patients with metastatic HR+/HER2- breast cancer. Please consider including the peer-reviewed data in the associated discussion sections and re-evaluating the Evidence Blocks Safety score from 2 to 3.

FDA status

Everolimus is approved for the treatment of postmenopausal women with advanced HR+/HER2- breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole.

Literature support


We appreciate the opportunity to provide this addendum for consideration by the NCCN Breast Cancer 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.

Sincerely,

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

Enclosures: Prescribing Information and copy of referenced primary literature; author disclosures included within references

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