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June 10, 2019

NCCN Guidelines Panel: Breast Cancer

On behalf of Puma Biotechnology, Inc., I respectfully request the NCCN Breast Cancer Guideline Panel review the enclosed recent presentation for NERLYNX® (neratinib) + capecitabine for HER2-positive metastatic breast cancer.

- Saura C, Oliveira M, Feng YH, et al. Neratinib plus capecitabine versus lapatinib plus capecitabine in patients with HER2-positive metastatic breast cancer previously treated with ≥2 HER2-directed regimens: Findings from the multinational, randomized, phase 3 NALA trial. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting. May 31-June 4, 2019; Chicago, IL.[1]

Specific Changes: No specific changes are requested. Please consider the Saura et al. presentation for your updating purposes.

FDA Clearance: neratinib has been approved for extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.[2] Neratinib is not approved for use in locally advanced / metastatic disease.

We would like to acknowledge the contributions of NCCN panel members who are also co-authors on this presentation.

Sincerely,

Deepa Lalla

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Head of Medical Affairs
Puma Biotechnology, Inc.

References

1. Saura C, Oliveira M, Feng YH, et al. Neratinib plus capecitabine versus lapatinib plus capecitabine in patients with HER2-positive metastatic breast cancer previously treated with ≥2 HER2-directed regimens: Findings from the multinational, randomized, phase 3 NALA trial. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting. May 31-June 4, 2019; Chicago, IL. *J Clin Oncol.* 2019;37:(suppl; abstr 1002). https://meetinglibrary.asco.org/record/170932

2. NERLYNX® (neratinib) tablets [Prescribing Information, June 2018] Puma Biotechnology, Inc. https://nerlynx.com/pdf/full-prescribing-information.pdf