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NCCN Guidelines Panel: Central Nervous System Cancers

On behalf of Puma Biotechnology, Inc., I respectfully request the NCCN Central Nervous System Cancers 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  $\geq 2$  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.<sup>1</sup>

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.<sup>2</sup> Neratinib is not approved for use in locally advanced / metastatic disease.

Sincerely,

Deepa Lalla, B.Pharm, PhD  
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  $\geq 2$  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>