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Puma Biotechnology Files NDS For NERLYNX In Canada

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The NDS recently passed the mandatory validation period by Health Canada, the country's federal regulator for drugs and health products, and has now entered the review period.

Puma Biotechnology, Inc., a biopharmaceutical company has announced that Health Canada has accepted for review the Company's New Drug Submission (NDS) for the medicinal product NERLYNX (neratinib) for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. The NDS recently passed the mandatory validation period by Health Canada, the country's federal regulator for drugs and health products, and has now entered the review period.

"Health Canada's acceptance of our NDS represents another important regulatory milestone in our commitment to increasing access to NERLYNX around the world to reduce disease recurrence following trastuzumab therapy in patients with early stage HER2-positive breast cancer," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We look forward to working with Health Canada during their review of our submission."

Neratinib, an oral irreversible pan-HER kinase inhibitor, was approved by the FDA in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed in the United States as NERLYNX. The drug also received a recommendation for marketing authorization from the Committee for Medicinal Products for Human Use (CHMP) in June 2018 and is being reviewed by the European Commission, which has the authority to approve medicines for the European Union.