

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
KNIGHT THERAPEUTICS INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1. Nerlynx (neratinib) is an oral protein kinase inhibitor approved for the extended adjuvant treatment of women with early-stage hormone receptor positive, HER2 overexpressed/amplified breast cancer within one year after completion of trastuzumab-based adjuvant therapy.
- 1.2. Health Canada first issued a Notice of Compliance for Nerlynx on July 16, 2019. Nerlynx was first sold in Canada commercially on December 12, 2019.
- 1.3. Nerlynx is available as a 40 mg/tablet (DIN 02490536).
- 1.4. The first reported patent pertaining to Nerlynx was granted on July 19, 2011. The last reported patent pertaining to Nerlynx is set to expire on November 2, 2030. Knight is the patentee for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board (“PMPRB”)

2.0 Application of the Guidelines

- 2.1 The Human Drug Advisory Panel (“HDAP”) recommended that Nerlynx be classified as a Moderate Improvement based on primary factors. The HDAP was of the view that there were no appropriate comparators to Nerlynx, therefore PMPRB Staff conducted a Median International Price Comparison (“MIPC”) test. The MIPC test established the Maximum Average Potential Price (“MAPP”).

3.0 Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (“VCU”) constitutes no admission by Knight that the price of Nerlynx is now nor was at any time since the date of first sale, excessive for the purposes of the *Patent Act*. It is Knight’s position that the price of Nerlynx has at all times been non-excessive.

4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 Pursuant to this VCU, Knight will undertake:
 - 4.1.1 To agree to the MAPP of \$43.7221 per tablet, which will establish the Introductory Benchmark Price (“IBP”);
 - 4.1.2 To agree to the 2021 Non-Excessive Average Price (“NEAP”) of \$44.5965 per tablet;
 - 4.1.3 To reduce the list price of Nerlynx to the MAPP of \$43.7221 per tablet within 30 days of the acceptance of this VCU;

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by PMPRB Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

VCU (March 2021)

- 4.1.4 To file evidence with PMPRB Staff within 30 days of the price reduction that customers have received notification that the price has been reduced; and
- 4.1.5 To ensure that the price of Nerlynx remains within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Name: Jody Engel

Position: Country Manager Canada

Patentee: Knight Therapeutics Inc.

Date: March 12, 2021

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