

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
PALADIN LABS INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1. Xydalba (dalbavancin) is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by gram-positive microorganisms.
- 1.2. Health Canada granted a Notice of Compliance for Xydalba on September 4, 2018. Xydalba was first sold in Canada on August 21, 2018.
- 1.3. Xydalba is supplied in vials containing 500 mg/vial (DIN 02480522).
- 1.4. The first reported patent pertaining to Xydalba was issued on August 5, 2014. The last reported patent pertaining to Xydalba is set to expire on April 26, 2025. Paladin Labs Inc. (Paladin) is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board.

2.0 Application of the Guidelines

- 2.1 The Human Drug Advisory Panel recommended that Xydalba be classified as a Slight or No Improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted for Xydalba which established the Maximum Average Potential Price for Xydalba.

3.0 Position of the Rights Holder

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Paladin that the price of Xydalba is now, nor was at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 Pursuant to this VCU, Paladin will undertake:
 - 4.1.1 To agree that the 2022, 2023 and 2024 Non-Excessive Average Price (NEAP) of Xydalba 500 mg/vial is \$957.1679 per vial;
 - 4.1.2 To ensure that the list price of Xydalba is reduced to \$957.1679 or lower by May 1, 2022;
 - 4.1.3 To offset the cumulative excess revenues from introduction to December 31, 2021, by making a payment of \$14,830.84 to Her Majesty in right of Canada, within 30 days of the acceptance of this VCU;

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a rights holder to comply with the terms of the VCU to close an investigation initiated by PMPRB Staff. Consideration of a VCU is an administrative procedure and does not constitute an admission or determination by the PMPRB that the price submitted by the rights holder, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.

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- 4.1.4 To make a payment to Her Majesty in right of Canada within 30 days of receiving PMPRB Staff's notification of any excess revenues as of December 31, 2022, as calculated based on the semi-annual price and sales data filed by Paladin; and
- 4.1.5 To ensure that the price of Xydalba remains within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Livio Di Francesco

Position: Vice President, General Manager

Rights Holder: Paladin Labs Inc.

Date: April 7, 2022

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