VOLUNTARY COMPLIANCE UNDERTAKING
OF
RECORDATI RARE DISEASES CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Ledaga (chlormethine hydrochloride) is indicated for the topical treatment of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) in adult patients who have received prior skin-directed therapy.

1.2. Health Canada first issued a Notice of Compliance for Ledaga 160 mcg/g (DIN 02516764) on June 8, 2021. Ledaga was first sold in Canada on June 13, 2019, through the Special Access Programme (SAP).

1.3. The first reported patent pertaining to Ledaga was granted on May 5, 2015, and is set to expire on March 14, 2026. Recordati Rare Diseases Canada Inc. ("Recordati") is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Guidelines

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

2.2 The introductory National Average Transaction Price (N-ATP) of Ledaga exceeded the MAPP by an amount which triggered the investigation criteria set out in the Guidelines. As of December 31, 2021, the cumulative excess revenues were determined to be $53,403.18.

3.0 Position of the Rights Holder

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Recordati that the prices of Ledaga are now, or were 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, Recordati will undertake:

4.1.1 To agree that the MAPP and Non-Excessive Average Prices (NEAPs) for Ledaga are:

Year	MAPP/NEAP
2019	$38.3360
2020	$39.2177
2021	$39.9844
2022	$40.2528

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.

4.1.2 To ensure that the list price of Ledaga is no higher than the 2022 NEAP of $40.2528 per gram within 30 days of the acceptance of this VCU;

4.1.3 To file evidence with PMPRB Staff within 30 days of the acceptance of the VCU that customers who purchased Ledaga from 2019 to 2021 have received notification that the price has been reduced;

4.1.4 To offset the excess revenues of $53,403.18 by making payments to customers who purchased Ledaga from 2019 to 2021, and to have these payments made within 30 days of the acceptance of this VCU, and to provide the PMPRB with documentation to confirm that such payments were made;

4.1.5 Within 30 days of the acceptance of this VCU, to advise each of the aforementioned customers of the repayment and to further advise that these actions are the result of an undertaking to the PMPRB, to provide a reference to the PMPRB website for the complete text of the VCU, and to provide copies of such notifications to the PMPRB forthwith;

4.1.6 To make a further payment to Her Majesty in right of Canada within 30 days of receiving PMPRB Staff's notification of any remaining cumulative excess revenues as of December 31, 2022, as calculated based on the total 2022 price and sales data filed by Recordati;

4.1.7 To ensure that the price of Ledaga remains within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Name: Max Johnson

Position: Managing Director

Rights Holder: Recordati Rare Diseases Canada Inc.

Date: May 24, 2022

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