

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
TAIHO PHARMA CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1. Lonsurf (trifluridine/tipiracil) is an antineoplastic agent indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with, or are not candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF biological agents, and if RAS wild-type, anti-EGFR agents.
- 1.2. Lonsurf was first sold in Canada on December 7, 2016 by Taiho Oncology Inc. through the Special Access Programme. Health Canada granted a Notice of Compliance to Taiho Pharma Canada Inc. (“Taiho”) for Lonsurf 28.19 mg/tablet (DIN 02472112) (“Lonsurf 28”) and Lonsurf 21.14 mg/tablet (DIN 02472104) (“Lonsurf 21”) (collectively, “Lonsurf”) on January 25, 2018.
- 1.3. The first reported patent pertaining to Lonsurf, Canadian Patent No. 2,914,999, was issued to Taiho Pharmaceutical Co., Ltd., on March 20, 2018. The last reported patent pertaining to Lonsurf will expire on June 17, 2034. Taiho is the patentee for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board.

2.0 Application of the Excessive Price Guidelines

- 2.1 The Human Drug Advisory Panel (HDAP) recommended that Lonsurf be classified as a Slight or No Improvement and identified Stivarga (regorafenib) as the most appropriate comparator for the purposes of conducting a Therapeutic Class Comparison (TCC) test for Lonsurf 28. The HDAP further recommended that the price of Lonsurf 21 be compared to Lonsurf 28 using the Reasonable Relationship (RR) test.
- 2.2 The TCC test established the Maximum Average Potential Price (MAPP) for Lonsurf 28. The introductory National Average Transaction Price (N-ATP) of Lonsurf 28 exceeded the MAPP by 222.0%, triggering the investigation criteria in the Guidelines. As of December 31, 2018, cumulative excess revenues were calculated to be \$71,107.64.
- 2.3 The RR test established the MAPP for Lonsurf 21. The introductory N-ATP of Lonsurf 21 exceeded the MAPP by 148.9%, triggering the investigation criteria in the Guidelines. As of December 31, 2018, cumulative excess revenues were calculated to be \$4,540.12.
- 2.4 The list prices of Lonsurf 28 and Lonsurf 21 were reduced to \$93.8500 and \$76.2500 per tablet, respectively, as of March 23, 2018.

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 Board 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.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Taiho that the prices of Lonsurf 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, Taiho will undertake:

4.1.1 To agree that the MAPPs and Non-Excessive Average Prices (NEAPs) for Lonsurf 21 and Lonsurf 28 are as follows:

Year	MAPP/NEAP
2017	\$76.2510
2018	\$77.3185
2019	\$78.5385

4.1.2 To reduce the list price of Lonsurf 28 to the 2019 NEAP of \$78.5385 per tablet or lower within 30 days of the acceptance of this VCU;

4.1.3 To file evidence with Board Staff within 30 days of the list price reduction that customers have received notification that the price has been reduced;

4.1.4 To ensure that the 2019 N-ATPs of Lonsurf do not exceed the 2019 NEAPs of \$78.5385 per tablet;

4.1.5 To offset the excess revenues accrued by Taiho in respect of Lonsurf as of December 31, 2018 by further reducing the 2019 N-ATPs below the 2018 NEAPs in accordance with Schedule 13 of the Guidelines;

4.1.6 To make a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining cumulative excess revenues as of December 31, 2019, as calculated based on the semi-annual price and sales data filed by Taiho; and

4.1.7 To ensure that the prices of Lonsurf remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

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VCU – September 2019

Name: Ross Glover
Position: General Manager
Patentee: Taiho Pharma Canada Inc.
Date: October 25, 2019

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