VOLUNTARY COMPLIANCE UNDERTAKING OF NOVARTIS PHARMACEUTICALS CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 Tasigna® 200mg indication at the date of first sale was for the treatment of accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib.

1.2 Health Canada issued a Notice of Compliance (NOC) for the sale of Tasigna® 200mg on September 9, 2008 (DIN 02315874) and sales in Canada commenced on September 30, 2008.

1.3 Canadian Patent No. 2,491,632 pertaining to Tasigna® was granted on November 10, 2009 and will expire on July 4, 2023. Novartis is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Tasigna® be classified as a category 3 new medicine and further recommended Sprycel® (dasatinib) as the only comparator for Tasigna®.

2.2 In accordance with the Board's *Guidelines* (Guidelines), a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the introductory price of Tasigna® exceeded the Guidelines. Specifically, the September to December 2008 introductory price of Tasigna® exceeded its maximum non-excessive (MNE) price of $37.7336 generating $10,244.24 in excess revenues in the introductory period.

2.3 The price of Tasigna® continued to exceed the Guidelines in subsequent reporting periods and as of December 31, 2009 there were cumulative excess revenues in the amount of $196,069.26.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission whatsoever by Novartis that the price of Tasigna® 200mg in Canada is now or was at any time excessive for purposes of the Patent Act. Novartis' position

remains that another comparator and another dosage should have been considered in the price review and the price of Tasigna® was set based on this premise.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 Notwithstanding paragraph 3.1 above, in order to settle the file, Novartis agrees, on a without prejudice basis and without admission of any liability whatsoever, to the following:

4.1.1 That the PMPRB has concluded that the 2008 and 2009 MNE prices and the 2010 National Non-Excessive Average Price (N-NEAP) for Tasigna® are as follows:

2008: $37.7336
2009: $37.8468
2010: $38.7147

4.1.2 To reduce the price of Tasigna® within 30 days of acceptance of this VCU so that it does not exceed the 2010 N-NEAP price of $38.7147 for the remainder of 2010;

4.1.3 To offset the cumulative excess revenues received by Novartis from September 30, 2008 to December 31, 2009 by making a payment to Her Majesty in right of Canada in the amount of $196,069.26 within 30 days of the acceptance of this VCU;

4.1.4 To offset any excess revenues received by Novartis from January 1, 2010 to the date of the implementation of the price reduction as per paragraph 4.1.2 by making a further payment to Her Majesty in right of Canada within 30 days of the filing of the price and sales data as required by the *Patented Medicines Regulations* in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Tasigna® at a price higher than the 2010 N-NEAP;

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers that the price reduction of Tasigna® is for purposes of ensuring adherence to the Guidelines, include a reference to the PMPRB Web Site for the complete text of this VCU, and provide copies of such notifications to Board Staff;

4.1.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Tasigna® has been reduced in a manner consistent with the terms of this VCU; and

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

Novartis Pharmaceuticals Canada Inc.

Signature: Original signed by

Company Officer: Alain Dostie

Position: Oncology General Manager

Date: October 12, 2010