VOLUNTARY COMPLIANCE UNDERTAKING
OF
HORIZON PHARMA IRELAND LIMITED
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Actimmune (interferon gamma 1-b) is not approved in Canada. Actimmune is made available by Horizon Pharma, Inc., through one or more subsidiaries and affiliates, (collectively, "Horizon") to Canadian patients under the Health Canada Special Access Programme ("SAP"). In the United States, Actimmune is approved for Chronic Granulomatous Disease ("CGD") and severe, malignant osteoporosis ("SMO"). It is currently being studied in Friederich's Ataxia, a rare disease with no treatments.

1.2. Horizon acquired the rights for Actimmune in 2014 from Vidara Therapeutics, which had acquired the product from lntermune in 2012.

1.3. Canadian Patent No. 1341561 pertaining to Actimmune was granted November 20, 2007 and will expire on November 20, 2024.

1.4. Sales in Canada (by Vidara Therapeutics under the SAP) commenced October 7, 2013.

1.5. Horizon is the patentee for purposes of the *Patent Act* and the Patented Medicines Prices Review Board ("PMPRB").

2.0 Application of the Excessive Price Guidelines ("Guidelines") – Position of the PMPRB Staff

2.1 The Human Drug Advisory Panel ("HDAP") recommended Actimmune be reviewed as a moderate improvement based on primary factors, and identified no comparator products.

2.2 In accordance with the Guidelines, the PMPRB Staff conducted the Median International Price Comparison ("MIPC") test. The results of this test indicate that the October to December 2013 introductory price at the national and market levels exceeded the Guidelines at a level that triggered the investigation criteria.

2.3 During the first period of sale in 2013, the National Average Transaction Price ("N-ATP") and the Market-Specific Average Transaction Prices ("MS-ATPs") of

Actimmune exceeded the MIPC generating $248,332.10 in excess revenues. The N-ATP and MS-ATPs of Actimmune continued to exceed the Guidelines in the subsequent reporting periods.

2.4 In April 2015, Horizon started to provide Actimmune at no cost to Canadian patients under the SAP.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") is a compromise between the PMPRB and Horizon. This VCU constitutes no admission by Horizon that the price of Actimmune is now, or was at any time since the date of the first sale of the medicine, excessive for purposes of the *Patent Act.*

4.0 Terms of the VCU

Horizon undertakes to:

4.1 Agree that the 2013 Maximum Average Potential Price ("MAPP") for Actimmune is $191.2110, and the 2014 and 2015 National Non-Excessive Average Prices ("N- NEAPs") for Actimmune are $195.0352 and $195.9913 respectively;

4.2 Agree that Actimmune will continue to be provided free of charge through Health Canada's SAP until December 31, 2017.

4.3 Make a payment to Her Majesty in right of Canada in the amount of $590,519.57 within 30 days of the acceptance of this VCU.

4.4 Agree that, should Horizon recommence sales of Actimmune in Canada on or after January 1, 2018 (and while a patented medicine), either Horizon or Board Staff may initiate a review of the price under the Guidelines that are applicable at the time of the review.

4.5 Ensure the price of Actimmune remains within PMPRB Guidelines in future periods in which Actimmune is under the PMPRB's jurisdiction.

Name: David G. Kelly

Position: Director

Patentee: Horizon Pharma Ireland Limited

Date: 12 May 2016