VOLUNTARY COMPLIANCE UNDERTAKING

OF ASTELLAS PHARMA CANADA, INC

TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Xospata (gilteritinib) is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation.

1.2. Health Canada granted a Notice of Compliance to Astellas Canada Pharma, Inc ("Astellas") for Xospata on December 23, 2019. Xospata was first sold in Canada on February 4, 2020.

1.3. Xospata is supplied in tablets containing 40 mg of gilteritinib. (DIN 02495058).

1.4. The first reported patent pertaining to Xospata was granted on February 28, 2017. The last reported patent pertaining to Xospata is set to expire on May 6, 2030. Astellas is the rights holder for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board.

2.0 Position of the Patentee

2.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Astellas that the price of Xospata is now, or 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*.

3.0 Terms of the Voluntary Compliance Undertaking

3.1 Pursuant to this VCU, Astellas will undertake:

3.1.1 To accept that the 2022, 2023 and 2024 Non-Excessive Average Price ("NEAP") of Xospata 40 mg/tablet is $276.6847 per tablet;

3.1.2 To offset the cumulative excess revenues from introduction to December 31, 2021 by making a payment of $400,000.00 to Her Majesty in right of Canada, within 30 days of the acceptance of this VCU;

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

Name: Frank Stramaglia

Position: General Manager

Patentee: Astellas Pharma Canada, Inc

Date: 28 February 2022