VOLUNTARY COMPLIANCE UNDERTAKING
OF
GLAXOSMITHKLINE INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Benlysta (belimumab) 120 mg/vial (DIN 02370050) and Benlysta 400 mg/vial (DIN 02370069) (collectively, "Benlysta") are indicated in addition to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus ("SLE").

1.2. The last reported Canadian Patent (No. 2,626,082) pertaining to Benlysta was issued to HUMAN GENOME SCIENCES, INC. on April 11, 2017, and will expire on October 5, 2026.

1.3. Health Canada issued a Notice of Compliance for Benlysta on July 6, 2011. Sales in Canada commenced August 24, 2011. Benlysta is currently marketed in Canada by GlaxoSmithKline Inc. ("GSK").

1.4. GSK is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board ("PMPRB").

2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel recommended Benlysta be classified as a Moderate Improvement based on primary factors. No comparators were identified for the purposes of conducting a domestic price test.

2.2 In accordance with the PMPRB's *Compendium of Policies, Guidelines and Procedures* ("*Guidelines*"), Median International Price Comparison ("MIPC") tests were conducted for each strength of Benlysta to set the Maximum Average Potential Prices ("MAPPs"). The introductory National Average Transaction Prices ("N-ATPs") for each strength of Benlysta were considered within the thresholds set out in the *Guidelines*.

2.3 The median international price used in the MIPC test was calculated on an interim basis as Benlysta was sold in fewer than five countries at the time it was first sold in Canada. A Post Interim Maximum Average Potential Price ("PI-MAPP") was calculated in the July to December 2012 reporting period when the same patented drug product of equal strength and dosage form was sold in at least five countries. Board Staff recalculated the National Non-Excessive Average Prices ("N-NEAPs") for that period and Benlysta continued to be within the thresholds set out in the Guidelines.

2.4 In 2017, both strengths of Benlysta triggered the investigation criteria set out in the *Guidelines* based on the CPI-Adjustment Methodology. As of December 31, 2017, cumulative excess revenues for both strengths were $108,112.85.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by GSK that the price of Benlysta 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*.

4.0 Terms of the Voluntary Compliance Undertaking

Pursuant to this VCU, GSK undertakes:

4.1 To agree that the N-NEAPs for 2017 and 2018, and the projected 2019 N-NEAPs for Benlysta are as follows:

Year	N-NEAP	
	120 mg	**400 mg**
2017	$263.1869	$877.3746
2018	$268.1545	$893.9350
2019	$270.0190	$900.0636

4.2 To ensure the 2019 N-ATPs do not exceed the calculated projected 2019 N-NEAPs, and to ensure that the prices in each market where Benlysta is sold in Canada are within the thresholds set out in the *Guidelines*;

4.3 To offset alleged excess revenues accrued by GSK as of December 31, 2017 by further ensuring that the 2019 N-ATPs of Benlysta are below the 2018 N-NEAPs; and

4.4 To ensure that the prices of Benlysta remains within the PMPRB's *Guidelines* in all future periods in which Benlysta is under the PMPRB's jurisdiction.

Signature: _____

Name: Yoo-Seok Hong

Position: VP & GM

Patentee: GlaxoSmithKline Inc.

Date: February 15, 2019