VOLUNTARY UNDERTAKING OF
SEAGEN CANADA INC.
TO THE PATENTED MEDICINE
PRICES REVIEW BOARD

1.0 Product Summary

1.1 Tukysa (tucatinib) is indicated, in combination with trastuzumab and capecitabine, for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received prior treatment with trastuzumab, pertuzumab, and trastuzumab emtansine, separately or in combination.

1.2 Tukysa is available as a 50 mg tablet (DIN 02499827) ("Tukysa 50 mg") and as a 150 mg tablet (DIN 02499835) ("Tukysa 150 mg"), collectively "Tukysa".

1.3 Health Canada granted a Notice of Compliance to Seagen Canada Inc. ("Seagen") for Tukysa on June 5, 2020. Tukysa 150 mg was first sold in Canada on August 27, 2020, and Tukysa 50 mg was first sold in Canada on October 8, 2020.

1.4 The first reported patent pertaining to Tukysa was granted on December 22, 2009. The last reported patent pertaining to Tukysa is set to expire on October 12, 2032. Seagen is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Position of the Rights Holder

2.1 This Voluntary Undertaking (VU) constitutes no admission by Seagen that the prices of Tukysa are now, or were at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VU binding upon any panel of the Board for the purposes of the *Patent Act*.

3.0 Terms of the Voluntary Undertaking

3.1 Pursuant to this VU, Seagen will undertake:

3.1.1 To accept the Lowest International Price Comparison ("LIPC") test as the price test in the determination of the Maximum Average Potential Price ("MAPP") for Tukysa 50 mg and Tukysa 150 mg;

3.1.2 To agree that that the MAPP and the 2020, 2021, and 2022 Non-Excessive Average Prices ("NEAPs") for Tukysa are as follows:

Year	Tukysa 50 mg (DIN 02499827)	Tukysa 150 mg (DIN 02499835)
2020	$35.4947	$106.4844
2021	$35.4947	$106.4844
2022	$35.4947	$106.4844

3.1.3. To reduce the list prices of Tukysa to the 2022 NEAPs described in 3.1.2 within 60 days of the acceptance of this VU;

3.1.4. To file evidence with PMPRB Staff within 30 days of the price reduction that customers have received notification that the price has been reduced; and

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

Signature: original signed _____

Name: Sandra Heller

Position: General Manager, Canada

Rights Holder: Seagen Canada Inc.

Date: 18-nov-22_____