VOLUNTARY COMPLIANCE UNDERTAKING
OF
LEADIANT BIOSCIENCES, INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 Adagen® (pegademase bovine) 250 units/mL injection (Adagen) is indicated for enzyme replacement therapy for adenosine deaminase (ADA) deficiency in patients with severe combined immunodeficiency disease (SCID) who are not suitable candidates for or who have failed bone marrow transplantation.

1.2 Adagen was first sold in Canada on January 1, 2010 through the Special Access Programme (SAP).

1.3 The first Canadian Patent pertaining to Adagen, No. 2,684,750, was issued on August 5, 2014.

1.4 The last reported patents pertaining to Adagen, Canadian Patent Nos. 2,684,749 and 2,684,750, lapsed on April 18, 2018. Leadiant Biosciences, Inc. (Leadiant) is the patentee for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 Leadiant first reported the existence of patents pertaining to Adagen in 2016.

2.2 Adagen was classified by the Human Drug Advisory Panel as a Breakthrough medicine. In accordance with the *Compendium of Policies, Guidelines and Procedures* (Guidelines), a Median International Price Comparison (MIPC) test was conducted. The results of this test indicated that the January to June 2010 introductory price of $3,771.0945 was within the thresholds set out in the Guidelines.

2.3 During the 2014 reporting period, the National Average Transaction Price (N-ATP) exceeded the National Non-Excessive Average Price (N-NEAP) of $3,889.5407 by 5.8%, and continued to exceed the N-NEAP in subsequent periods. As of April 18, 2018, potential excess revenues were calculated to be $3,269,904.67.

3.0 Position of the Patentee and the Board

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Leadiant that the price of Adagen 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

4.1 Pursuant to this VCU, Leadiant will undertake:

4.1.1 To make payments totaling $3,269,904.67 directly to the public payers that funded Canadian purchases of Adagen, based on Leadiant's records of the historic distribution of these purchases, as provided to the PMPRB. All payments shall be made within 60 days of acceptance of this VCU. Leadiant shall notify the PMPRB of each payment made directly to the public payers pursuant to this VCU within 30 days of making any such payment.

4.1.2 Within 30 days of acceptance of this VCU, to advise each of the aforementioned payers of the repayment specific to their public drug plan and to further advise that these actions are the result of an undertaking to the PMPRB, to provide a reference to the PMPRB website for the complete text of the VCU, and to further provide copies of such notifications to the PMPRB forthwith.

4.1.3 To notify the PMPRB in the event that any other patents pertaining to Adagen are issued.

Name: Michael Minarich

Position: CEO

Patentee: Leadiant Biosciences, Inc.

Date: October 7, 2019