

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
AKCEA THERAPEUTICS CANADA  
TO  
THE PATENTED MEDICINE PRICES REVIEW BOARD**

**1.0 Product Summary**

- 1.1. Tegsedi (inotersen) is indicated for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR).
- 1.2. Health Canada granted a Notice of Compliance to Akcea Therapeutics Canada (“Akcea”) for Tegsedi on October 3, 2018. Tegsedi was first sold in Canada on November 12, 2019.
- 1.3. Tegsedi is an intravenous solution available in 1.5 milliliter prefilled syringes containing 284 milligrams of inotersen (DIN 02481383).
- 1.4. The first reported patent pertaining to Tegsedi was granted on February 27, 2018. The last reported patent pertaining to Tegsedi is set to expire on April 29, 2031. Akcea is the patentee 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 Akcea that the price of Tegsedi 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, Akcea will undertake:
  - 3.1.1 To accept that the Lowest International Price Comparison (“LIPC”) as the price test in the determination of the Maximum Average Potential Price (“MAPP”) for Tegsedi;
  - 3.1.2 To reduce the list price of Tegsedi , within 30 days of the acceptance of this VCU, for the remainder of the years 2020 and for 2021, to the 2020 Non-Excessive Average Price (“NEAP”) of \$8,043.4874 per syringe;
  - 3.1.3 To ensure that the price of Tegsedi remains within the PMPRB’s Guidelines in all future periods in which it is under the PMPRB’s jurisdiction.

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

Signature: \_\_\_\_\_

Name: Jared Rhines

Position: President

Patentee: Akcea Therapeutics Canada

Date: 27 August 2020

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