

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
ALNYLAM PHARMACEUTICALS INC.  
TO  
THE PATENTED MEDICINE PRICES REVIEW BOARD**

**1.0 Product Summary**

- 1.1. Onpattro (patisiran) is indicated for the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis).
- 1.2. Health Canada granted a Notice of Compliance to Alnylam Pharmaceuticals Inc. (“Alnylam”) for Onpattro on June 7, 2019. Onpattro was first sold in Canada on October 4, 2019.
- 1.3. Onpattro is an intravenous liquid available in 5 milliliter vials containing 10 milligrams of patisiran, at a concentration of 2 milligrams per milliliter (DIN 02489252).
- 1.4. The first reported patent pertaining to Onpattro was granted on November 24, 2015. The last reported patent pertaining to Onpattro is set to expire on June 10, 2030. Alnylam 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 Alnylam that the price of Onpattro 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, Alnylam will undertake:
  - 3.1.1 To agree that the Lowest International Price Comparison (“LIPC”) is the most appropriate price test in the determination of the Maximum Average Potential Price (“MAPP”) for Onpattro;
  - 3.1.2 To reduce the list price of Onpattro for the years 2020 and 2021, to the 2020 Non-Excessive Average Price (“NEAP”) OF \$2,100.4813 per milliliter or lower within 30 days of the acceptance of this VCU;
  - 3.1.3 To ensure that the price of Onpattro 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.

Name: Barry Greene  
Position: Barry Greene  
Patentee: Alnylam Pharmaceuticals Inc.  
Date: 31 August 2020

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