**From:** Summers, Patricia <psummers@shire.com>
**Sent:** Wednesday, September 26, 2018 3:21 PM
**To:** AGO - High Cost Prescription Drugs
**Cc:** Serewicz, Denise M
**Subject:** Introduction of New Prescription Drug Notice 2

Jill S. Abrams
Assistant Attorney General
Director, Consumer Protection Division
Vermont Office of the Attorney General
109 State Street
Montpelier, VT 05609

Dear Assistant Attorney General Abrams:

Further to the notice filed on August 28, 2018, Dyax Corp., a member of the Shire group of companies, located at 300 Shire Way, Lexington, MA 02421 ("Shire") hereby submits the following information pursuant to 18 V.S.A. § 4637(c). In accordance with Section 4637 (d), Shire's submission is limited to information that is in the public domain or publicly available.

| **Drug Name** | **NDC#** | **Vial presentation available for purchase** | **Wholesale Acquisition Cost** | **First date** |
|---|---|---|---|---|
| TAKHZYRO™ (lanadelumab-flyo) injection | 47783-0644-01 | 300 mg/2 mL (150 mg/mL) | 22,070.00 | August 28, 2018 |

1. Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally:

**RESPONSE:** Shire's marketing and pricing plans are confidential and proprietary, and not available in the public domain or publicly available.

2. The estimated volume of patients who may be prescribed the drug:

**RESPONSE:** Shire's estimates regarding the volume of potential patients who may be prescribed the drug are not available in the public domain or publicly available. TAKHZYRO™ (lanadelumab-flyo) injection is approved for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years of age and older. HAE is a rare, genetic and potentially life-threatening disorder that can result in recurrent attacks of edema (swelling) in various parts of the body. As a general matter, HAE occurs in about 1 in 10,000 to 1 in 50,000 people and it has been estimated that ~6,000 people in the US suffer from HAE (see **HAEA website**; Bernstein JA. HAE update: epidemiology and burden of disease. *Allergy Asthma Proc* 2013;34:3-6; Zuraw BL, Banerji A, Bernstein JA*, et al*. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clin Immunol Pract* 2013a;1:458-467.**)**
Not all HAE patients are treated prophylactically.

3. Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval:

**RESPONSE:** TAKHZYRO™ (lanadelumab-flyo) injection received Fast Track, Breakthrough Therapy, and Orphan Drug Designations by the FDA.

4. The date and price of acquisition if the drug was not developed by the manufacturer.

**RESPONSE:** Not applicable. TAKHZYRO™ (lanadelumab-flyo) injection was developed by the manufacturer.

Patients are at the center of everything we do at Shire. We look forward to continuing to work with Vermont to ensure affordable and appropriate access to Shire therapies.

Sincerely,

Patricia Summers
Director, Government Pricing and Contracting
US Pricing and Market Access
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