

## Takhzyro<sup>™</sup> (lanadelumab-flyo) – New orphan drug approval

- On August 23, 2018, the <u>FDA announced</u> the approval of <u>Shire's Takhzyro (lanadelumab-flyo)</u>, for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.
- HAE is a rare and serious genetic disease that affects an estimated 1 in 50,000 men and women. HAE causes recurrent, unpredictable episodes of severe swelling in different areas of the body, including the stomach, limbs, face and throat. Type I HAE is the most common, and accounts for 85% of cases.
- Lanadelumab-flyo is a fully human monoclonal antibody that binds plasma kallikrein and inhibits its
  proteolytic activity. Plasma kallikrein is an enzyme which is chronically uncontrolled in people with
  HAE.
- The efficacy and safety of Takhzyro were demonstrated in a 26-week placebo-controlled study of 125 patients with type 1 or 2 HAE. The primary endpoint was the reduction in mean HAE attack rates vs. placebo.
  - Patients who received Takhzyro had clinically meaningful and statistically significant reductions in the mean rate of monthly HAE attacks vs. placebo. Mean rate of monthly HAE attacks: Takhzyro 150 mg every 4 weeks: 0.48; 300 mg every 4 weeks: 0.53; 300 mg every 2 weeks: 0.26 vs. 1.97 with placebo (p < 0.001 for all Takhzyro groups vs. placebo).</li>
- A warning and precaution of Takhzyro includes hypersensitivity reactions.
- The most common adverse reactions with Takhzyro use were injection site reactions, upper respiratory infections, headache, rash, myalgia, dizziness, and diarrhea.
- The recommended starting dose of Takhzyro is 300 mg administered subcutaneously every 2 weeks.
  - A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (eg, attack free) for more than 6 months.
  - Takhzyro is intended for self-administration or administration by a caregiver. The patient or caregiver should be trained by a healthcare professional.
- Shire has launched Takhzyro. Takhzyro is available as a 300 mg/2 mL solution in a single-dose vial.



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