Takhzyro® (lanadelumab-flyo) – Expanded indication

- On February 3, 2023, the FDA approved Takeda"—s Takhzyro (lanadelumab-flyo), for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 2 years and older.

    — Takhzyro was previously approved for this indication in adult and pediatric patients 12 years and older.

- The approval of Takhzyro for the expanded indication was supported by extrapolation of efficacy data from an adequate and well controlled study in adult and pediatric (12 to less than 18 years of age) patients, with additional pharmacokinetic analyses showing similar drug exposures between adults (> 18 years of age) and pediatric patients (2 to less than 12 years of age), and safety and pharmacodynamic data from an open-label study in pediatric patients with HAE aged 2 to less than 12 years that enrolled 21 patients (4 patients were aged 2 to less than 6 years and 17 patients were 6 to less than 12 years of age). The pharmacodynamic response observed in this trial for pediatric patients 2 to less than 12 years of age was similar to that seen in adult and pediatric patients 12 years of age and older.

- The recommended starting dosage of Takhzyro in pediatric patients 6 to less than 12 years of age is 150 mg administered subcutaneously (SC) once every 2 weeks. A dosing interval of 150 mg every 4 weeks may be considered if the patient is well-controlled (eg, attack free) for more than 6 months.

- The recommended dosage of Takhzyro in pediatric patients 2 to less than 6 years of age is 150 mg administered SC once every 4 weeks.

- Refer to the Takhzyro drug label for dosing for adult and pediatric patients 12 years of age and older.