Generic Name:
Lanadelumab
Trade Name:
Takhzyro
Company:
Shire
Notes:

FDA approved lanadelumab, the first monoclonal antibody approved in the United States to treat patients aged 12 years and older with types I and II hereditary angioedema (HAE).

HAE is a rare and serious genetic disease that affects an estimated 1 in 50,000 men and women with low levels of and poorly functioning C1-INH proteins. This results in recurrent, unpredictable episodes of severe swelling in different areas of the body, including the stomach, limbs, face, and throat.

Type I is the most common and accounts for 85% of cases. Symptoms of HAE typically begin in childhood and worsen following puberty. Some patients may have many attacks each month, while others will go months without an attack.

FDA based its approval on data from a multicenter, randomized, double-blind, placebo-controlled, parallel-group study in 125 patients with HAE. Patients who received lanadelumab had clinically meaningful and statistically significant reductions in the rate of investigator-confirmed HAE attacks compared with placebo over a 6-month treatment period.

The most common adverse reactions in clinical trials were injection-site reactions, upper respiratory infections, headache, rash, muscle pain, dizziness, and diarrhea.

Medication Monitor Categories:
New Drug Approvals