BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Takeda's TAKHZYRO (lanadelumab) approved in Japan

March 29, 2022 | News

Approval based on results of Global Phase 3 HELP Study, Phase 3 HELP OLE and a Phase 3 Study in Japanese patients evaluating the efficacy and safety of TAKHZYRO



Takeda has received approval from the Ministry of Health, Labour and Welfare (MHLW) for TAKHZYRO (lanadelumab) subcutaneous injection 300mg syringes for prophylaxis against acute attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older in Japan.

Hereditary angioedema (HAE) is a rare genetic disorder that results in recurring attacks of oedema – swelling – in various parts of the body, including the abdomen, face, feet, genitals, hands and throat. The swelling can be debilitating and painful. Attacks that obstruct the airways can cause asphyxiation and are potentially life threatening. HAE affects an estimated 1 in 50,000 people worldwide. In Japan, it is estimated that between 2,000 and 3,000 people are living with HAE, but only approximately 450 have been diagnosed due to low awareness of the disorder in the country.

This approval is primarily based on results of the global Phase 3 HELP (Hereditary Angioedema Long-term Prophylaxis) Study and the Phase 3 HELP Study Open-label Extension (OLE), in addition to results of a Phase 3 study evaluating the efficacy and safety of TAKHZYRO in Japanese patients. Combined, these studies have demonstrated the efficacy and safety profile of TAKHZYRO as a preventive treatment for HAE attacks.

TAKHZYRO received its first approval for the prevention of HAE attacks in patients 12 years and older in 2018 in the United States and in the European Union, and is now approved in more than 50 countries. TAKHZYRO is intended for self-administration or administration by a caregiver once trained by a healthcare professional. TAKHZYRO is supported by a robust clinical development program, which includes one of the largest prevention studies in HAE with the longest active treatment duration with additional regulatory submissions ongoing worldwide.