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Shire receives USFDA nod for TAKHZYRO

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TAKHZYRO is the only monoclonal antibody (mAb) that provides targeted inhibition of plasma kallikrein, an enzyme which is chronically uncontrolled in people with hereditary angioedema, to help prevent attacks



Shire, the leading global biotechnology company focused on rare diseases, has announced that following priority review, the U.S. Food and Drug Administration (FDA) has approved TAKHZYRO (lanadelumab-flyo) injection, 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.[1,2,3,4]

“HAE attacks are painful, debilitating, and potentially life threatening. TAKHZYRO provides the HAE community with a new option for the prevention of HAE attacks,” said Anthony J. Castaldo, President, U.S. Hereditary Angioedema Association. “We are grateful for the time and effort put forth by the patients and researchers who participated in the clinical trial program that enabled this important addition to the HAE treatment landscape.”

TAKHZYRO is the only monoclonal antibody (mAb) that provides targeted inhibition of plasma kallikrein, an enzyme which is chronically uncontrolled in people with HAE, to help prevent attacks. The recommended starting dose of TAKHZYRO is 300 mg every two weeks. A dosing interval of 300 mg every four weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than six months.

Andreas Busch, Ph.D., Executive Vice President, Head of Research and Development at Shire said: “With the approval of TAKHZYRO, HAE patients have an innovative treatment that works differently than current options to help prevent attacks. Based on an exploratory and post hoc analysis, after six doses of TAKHZYRO 300 mg every two weeks, 77% or nearly 8 of 10 patients had zero attacks. This approval reinforces our ongoing commitment to developing novel therapies that have a meaningful impact on patients. Looking to the future, we continue to work towards our goal of a world in which those living with HAE can aim for zero attacks.”

Shire added TAKHZYRO to its HAE portfolio with the acquisition of Dyax Corp., which was completed in January 2016 in an all cash transaction valued at approximately $5.9 billion. Under the terms of the acquisition, the non-tradable contingent value right (CVR) received by Dyax shareholders will now pay $4.00 in cash per Dyax share as a result of the FDA approval of TAKHZYRO (formerly DX-2930).