



Veeva certified: 2 July 2024

## **Teva Announces First Phase 3 Evidence of Efficacy and Safety of an Anti-CGRP Monoclonal Antibody in Children in AJOVY® (fremanezumab) SPACE Trial for Prevention of Episodic Migraine**

19 JULY 2024

- *SPACE pediatric Phase 3 study met its primary end point for efficacy with a significantly greater reduction in Monthly Migraine Days compared to placebo*
- *Efficacy is consistent with AJOVY (fremanezumab) pivotal Phase 3 and Real-World Evidence studies in adults with no new emergent safety signals observed*
- *Full data to be presented at a medical meeting later in 2024*

**TEL AVIV, Israel - BUSINESS WIRE** - Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) announced today positive topline results from its Phase 3 SPACE study evaluating the efficacy of AJOVY (fremanezumab) for the prevention of episodic migraine in children and adolescent patients aged 6-17 years. The trial met its primary end point with AJOVY (fremanezumab) achieving a statistically significant superior efficacy over 12 weeks of treatment compared to placebo. Safety data was consistent with that observed in adult populations, with no emergent safety signals. Full data from the SPACE study will be presented at a medical meeting later this year.

"The study outcome is excellent news in light of the unmet need for effective preventive therapies for children and adolescents living with migraine who are greatly impacted by this debilitating disease," said Eric A. Hughes, MD, PhD, Executive Vice President, Global R&D and Chief Medical Officer, at Teva Pharmaceuticals. "The SPACE data supports our ambitions to bring the proven benefits of AJOVY to children and adolescent patients who have fewer treatment options available to them. I am pleased to see that AJOVY is continuing to demonstrate its efficacy and safety in different migraine populations, including pediatric patients."

The SPACE data are the first Phase 3 trial evidence of safety and efficacy of an anti-CGRP monoclonal antibody for the treatment of migraine in a pediatric population. The results have particular significance given the lack of preventive migraine treatments approved for use in

children and adolescent populations. Teva continues to study the impact of AJOVY (fremanezumab) in pediatric patients with chronic migraine.

Migraine is common among children, with an overall estimated prevalence of 7.7%. The prevalence increases from 5% among children aged 5 to 10 years to approximately 15% among adolescents.<sup>1</sup> Migraine can cause significant disability in children and adolescents, leading to absence from school, impaired educational performance and missed social activities.<sup>1</sup>

### **About SPACE**

SPACE is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study comparing the efficacy, safety, and tolerability of subcutaneous administration of fremanezumab versus placebo over a 12 week period for the preventive treatment of episodic migraine in 235 pediatric patients aged 6 to 17 years.

### **About AJOVY®**

AJOVY is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month. AJOVY is available as a 225 mg/1.5 mL single dose injection in a pre-filled syringe or, in some countries, in a pre-filled pen. Two dosing options are available: 225 mg once monthly administered as one subcutaneous injection (monthly dosing), or 675 mg every three months (quarterly dosing), which is administered as three subcutaneous injections. AJOVY can be administered either by a healthcare professional or at home by a patient or caregiver. No starting dose is required to begin treatment.

### **About Teva**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a global pharmaceutical leader with a category-defying portfolio, harnessing our generics expertise and stepping up innovation to continue the momentum behind the discovery, delivery, and expanded development of modern medicine. For over 120 years, Teva's commitment to bettering health has never wavered. Today, the company's global network of capabilities enables its ~37,000 employees across 58 markets to push the boundaries of scientific innovation and deliver quality medicines to help improve health outcomes of millions of patients every day. To learn more about how Teva is all in for better health, visit [www.tevapharm.com](http://www.tevapharm.com)

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to: our ability to successfully develop and commercialize AJOVY for the prevention of migraine in children and adolescent patients; our ability to successfully compete in the marketplace including our ability to develop and commercialize additional pharmaceutical products; our ability to successfully execute our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generics medicines; and other factors discussed in this press release, in our quarterly report on Form 10-Q for the first quarter of 2024, and in our Annual Report on Form 10-K for the year ended December 31, 2023, including in the sections captioned "Risk Factors." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information

contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

**References:**

1. Pediatric Migraine, An Update. Greene, Kaitlin. et al; Neurology clinics, Volume 37, Issue 4, 815-833. August 31, 2019. <https://doi.org/10.1016/j.ncl.2019.07.009>

**Contact:**

Eden Klein, Teva Global Corporate Communications: +972 (3) 906 2645