

## Teva to Present New Long-Term Data on Efficacy and Safety of Fremanezumab at 2019 American Academy of Neurology Annual Meeting

Findings describe the efficacy and safety results of clinical trials of fremanezumab through 12 months of treatment in patients with chronic and episodic migraine

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today announced results from new long-term analyses of the efficacy and safety of fremanezumab, being presented at the 71st Annual Meeting of the American Academy of Neurology (AAN) in Philadelphia from May 4-10, 2019.

The findings, presented across 13 abstracts at this year's meeting, describe the primary and other key endpoints, as well as pooled and subgroup data from a 52-week, multicenter, randomized, double-blind, parallel group long-term extension study that evaluated fremanezumab in adults with migraine. The results presented include data on the efficacy of fremanezumab observed through 12 months of treatment in patients with migraine, including populations with inadequate responses to multiple classes of preventive medications, quality of life and the safety profile.

"We are pleased to join the neurology community at this year's AAN meeting and share these long-term data results on fremanezumab as a preventive treatment option for patients living with migraine," said Danny McBryan, Senior Vice President, Head of Global Medical Affairs and Pharmacovigilance at Teva. "These data, studied in a wide range of migraine patient populations, add to our growing body of evidence about fremanezumab, and further demonstrate our ongoing commitment to improving the lives of those who suffer from migraine."

### Analysis design

The long-term extension study of fremanezumab included patients rolled over from two placebo-controlled studies, as well as 312 newly enrolled patients. Patients were assigned to either monthly dosing (225 mg monthly; chronic migraine: starting dose of 675 mg), or quarterly dosing (675

mg every three months). A total of 1,890 patients were enrolled and 1,494 completed 12 months of treatment. Patients included those with chronic migraine (CM) and episodic migraine (EM).

### Analysis highlights

A selection of key data points of note across the analyses are summarized below.

#### Long-term efficacy and safety results:

In an analysis of the 1,110 patients included in the study with CM, those achieving  $\geq 50$  percent reduction in monthly average number of headache days of at least moderate severity at month 12 was 54 percent of patients in the quarterly dosing arm and 59 percent in the monthly dosing arm. Those achieving  $\geq 50$  percent reduction in monthly average number of migraine days at month 12 was 53 percent of patients in the quarterly dosing arm and 57 percent of patients in the monthly dosing arm. Additionally, patients with CM showed decreased use of any acute headache medication and improvements in disability that were observed through the one-year treatment period.<sup>1</sup>

An analysis of the 780 patients included in the study with EM demonstrated that patients achieving  $\geq 50$  percent reduction in migraine days at month 12 was 66 percent in the quarterly dosing arm and 68 percent in the monthly dosing arm. Similar response rates were observed for headache days of at least moderate severity. Similar to the results observed in CM patients, patients with EM also showed decreased use of any acute headache medication and improvements in disability that were observed through the one-year treatment period.<sup>2</sup>

Additionally, Teva conducted a post-hoc efficacy analysis of 813 patients with CM at baseline, of which 67 percent (548) reverted to EM during the study period. In this subgroup, the average change in the monthly number of headache days of at least moderate severity from baseline to month 12 was -8.8 for the quarterly dosing arm and -8.5

for the monthly dosing arm. The mean change in the monthly number of migraine days from baseline to month 12 was -10.3 for quarterly and -10.4 for monthly. Overall, monthly headache days, migraine days and days of acute headache medication use decreased progressively from month six and through month 12 in both dosing groups.<sup>3</sup>

A safety analysis of all 1,890 patients enrolled in the one-year study demonstrated that the most common adverse events (AEs) were injection-site reactions, which occurred in 26-33 percent of all patients. Four percent of patients discontinued due to adverse events.<sup>4</sup>

#### Quarterly dosing persistency results:

Teva also assessed whether patients in the quarterly dosing arm experienced any pattern of decreased efficacy during the third month after injection (also known as “wearing off” effect). In the analysis of 1,103 CM patients and 775 EM patients, outcomes with quarterly dosing of fremanezumab were comparable to outcomes with monthly dosing.<sup>5</sup> Quality of life results:

The effect of fremanezumab on headache-related disability, quality-of-life and patient satisfaction in CM and EM patients was assessed using clinically validated questionnaires. Overall, long-term treatment with fremanezumab suggested potential improvements in disability and quality of life in patients with both CM and EM.<sup>6</sup> About fremanezumab

AJOVY® (fremanezumab-vfrm) injection is indicated for the preventive treatment of migraine in adults.

## IMPORTANT SAFETY INFORMATION

**Contraindications:** AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients.

**Hypersensitivity Reactions:** Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria were reported with AJOVY in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. If a hypersensitivity reaction occurs, consider discontinuing AJOVY and institute appropriate therapy.

**Adverse Reactions:** The most common adverse reactions (≥5% and greater than placebo) were injection site reactions.

Please click here for full Prescribing Information for AJOVY® (fremanezumab-vfrm) injection.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing

medicines to improve people's lives for more than a century. We are a global leader in generic and specialty medicines with a portfolio consisting of over 35,000 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at [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. Important factors that could cause or contribute to such differences include risks relating to:

our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; competition for our specialty products, especially COPAXONE®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; the uncertainty of commercial success of AJOVY® and AUSTEDO®; competition from companies with greater resources and capabilities; efforts of pharmaceutical companies to limit the use of generics, including through legislation and regulations; consolidation of our customer base and commercial alliances among our customers; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our products, both from competing products and increased regulation; delays in launches of new products and our ability to achieve expected results from investments in our product pipeline; our ability to take advantage of high-value opportunities; the difficulty and expense of obtaining licenses to proprietary technologies; and the effectiveness of our patents and other measures to protect our intellectual property rights; our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us; our business and operations in general, including: failure to

effectively execute our restructuring plan announced in December 2017; uncertainties related to, and failure to achieve, the potential benefits and success of our new senior management team and organizational structure; harm to our pipeline of future products due to the ongoing review of our R&D programs; our ability to develop and commercialize additional pharmaceutical products; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; compliance with sanctions and other trade control laws; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the failure to recruit or retain key personnel; variations in intellectual property laws that may adversely affect our ability to manufacture our products; challenges associated with conducting business globally, including adverse effects of political or economic instability, major hostilities or terrorism; significant sales to a limited number of customers in our U.S. market; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; and our prospects and opportunities for growth if we sell assets ; compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; governmental investigations into selling and marketing practices; potential liability for patent infringement; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks; other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; potential significant increases in tax liabilities; and the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; and other factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2018, including the sections thereof 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:1Mcallister P, et al. Long-Term Impact of Fremanezumab on Response Rates, Acute Headache Medication Use, and Disability in Patients With Chronic Migraine: Results of a 1-Year Study. Presented at: 2019 AAN Annual Meeting, Philadelphia, PA.2Brandes JL, et al. Long-Term Impact of

Fremanezumab on Response Rates, Acute Headache Medication Use, and Disability in Patients With Episodic Migraine: Results of a 1-Year Study. Presented at: 2019 AAN Annual Meeting, Philadelphia, PA.3Lipton R, et al. Long-Term Efficacy of Fremanezumab in Patients Who Reverted From a Chronic to an Episodic Migraine Classification. Presented at: 2019 AAN Annual Meeting, Philadelphia, PA.4Ning X, et al. Long-Term Safety of Fremanezumab: Results of a 1-Year Study. Presented at: 2019 AAN Annual Meeting, Philadelphia, PA.5Blaise CA, et al. Quarterly Administration of Fremanezumab Does Not Show "Wearing Off" Effect During Third Month After Injection. Presented at: 2019 AAN Annual Meeting, Philadelphia, PA.6Cohen J, et al. Long-Term Impact of Fremanezumab on Headache-Related Disability, Quality of Life, and Patient Satisfaction in Episodic Migraine and Chronic Migraine Presented at: 2019 AAN Annual Meeting, Philadelphia, PA.

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