Teva presenterar positiva resultat gällande förbättring av funktionsnedsättning och livskvalitet från fas IIIb-studien FOCUS där Fremanezumab studerades hos vuxna med migrän

Dessa resultat inkluderar reduktion av månatliga genomsnittliga migrändagar; reduktion av migränrelaterade symptom; samt förbättring av depressionsstatus, arbetsproduktivitet och aktivitetsnedsättning

Jerusalem, 2nd July 2019 — Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) presenterade stolt forskningsresultat från studien FOCUS under kongressen EAN (the European Academy of Neurology) i Oslo, Norge, den 29 Juni till den 2 Juli 2019.

Resultaten, som visades för första gången under EAN, sammanfattar pre-specificerade endpoints från fas IIIb-studien FOCUS. Denna studie utvärderade Fremanezumabs effekt och säkerhet gällande preventiv behandling av migrän hos vuxna patienter som tidigare behandlats, utan tillfredsställande resultat, med två till fyra olika klasser av preventiv behandling.

Director of the Headache Clinical Unit and Research Group at Vall d'Hebron Hospital and Institute of Research (VHIR), Patricia Pozo Rosich, MD, PhD, said: "The FOCUS study results demonstrate the potential of fremanezumab in addressing the burden of migraine in this difficult-to-treat patient population and I am glad to see the exploratory data being presented at EAN which includes quality of life and disability results, which also improved in these patients who have a substantial daily burden due to their migraine."

"Migraine is the second leading cause of years lived with disability worldwide with profound impact on patients, their families and friends, and on society as a whole. Data from the FOCUS study disclose the results of fremanezumab on a range of quality of life and disability measures as well as demonstrating a significant reduction in the number of headache hours and days suffered by patients and on a spectrum of associated symptoms", commented Joshua M. Cohen, MD, MPH, FAHS, Global Medical Lead for Migraine & Headache.

During the EAN Congress, Teva presented FOCUS exploratory endpoints results which include:

Reduced Migraine Days
Data on efficacy and clinically meaningful responses to fremanezumab showed reductions in the monthly average number of migraine days and sustained ≥50% response rates over three months were significantly greater with fremanezumab versus placebo in the study.

Migraine-related Symptoms
In the FOCUS study data being presented at EAN, both monthly and quarterly fremanezumab dosing reduced migraine-related symptoms of nausea or vomiting and photophobia and phonophobia versus placebo in the study cohort.

Disability
The impact of fremanezumab on headache-related disability was assessed using internationally regarded questionnaires as exploratory endpoints of the FOCUS trial. Substantial improvements in headache-related disability were seen in those patients taking the active drug compared with placebo - with both fremanezumab dosing regimens - and reductions from baseline in the disability score were greater compared with placebo.

Quality of Life

IR Contacts	**Global**	Kevin C. Mannix	(215) 591-8912
PR Contacts	**US**	Doris Saltkill	(+1) 816-391-8881
	Europe	Fiona Cohen	(31) 6 2008 2545
	Israel	Yonatan Beker	972 (54) 888 5898

Migraine invariably has a negative effect on quality of life and the study looked at the effect of fremanezumab on migraine-specific health-related quality of life and health status in patients as exploratory endpoints. Mean changes from baseline using internationally regarded quality of life questionnaires were seen four weeks after the third dose. Improvements were seen from baseline in all domains, and scores were greater with both fremanezumab dosing regimens versus placebo.

Depression
Migraine patients are estimated to be approximately 2-4 times more likely to have depression than the general population. Depression status was evaluated as an exploratory endpoint in the study. Improvements in depression status were observed with monthly fremanezumab versus placebo, and to a lesser degree with the quarterly dose.

Productivity
Work productivity and activity impairment were evaluated using a globally accepted questionnaire to ascertain whether fremanezumab had a positive impact. During the 4 weeks after the third study drug dose, greater improvements from baseline were observed with both fremanezumab dosing regimens versus placebo (nominal p-values all $P<0.05$) assessing absenteeism and presenteeism.

Medication Use
The use of any medication, and migraine-specific acute headache medication such as triptans and ergot compounds, respectively, were evaluated and results show that both dosing regimens of fremanezumab significantly reduced acute headache medication use of either kind.

The study also investigated the efficacy of fremanezumab in patients who had previously failed topiramate or onabotulinumtoxinA. Reductions from baseline in the monthly average number of migraine days during the 12-week treatment period were significantly greater with both fremanezumab regimens versus placebo in this subset of patients.

The full results of the FOCUS study will be submitted for publication later in 2019.

The full EAN online programme can be accessed via the congresses official website:
https://www.ean.org/oslo2019/Schedule.3659.0.html

-ENDS-

Notes to Editors:
About FOCUS
The Phase IIIb FOCUS study of fremanezumab was the first and largest study of a migraine preventive treatment in a difficult-to-treat population of adults with episodic or chronic migraine (EM or CM) who had documented inadequate response to 2-4 classes of migraine preventive medications. The study is a multicenter, randomized, double-blind, parallel-group, placebo-controlled study that evaluated the efficacy, safety, and tolerability of quarterly and monthly treatment with fremanezumab, compared to placebo. Adult patients with chronic migraine or episodic migraine who have responded inadequately to two to four classes of prior preventive treatments were enrolled in the study.

Inadequate response is defined as: lack of efficacy after at least three months of therapy at a stable dose; or the patient cannot tolerate the drug; or the drug is contraindicated; or the drug is not suitable for the patient. The classes of medications include: beta-blockers, anticonvulsants, tricyclics, calcium channel blockers, angiotensin II receptor antagonists, onabotulinumtoxinA, and valproic acid.

In the study, chronic migraine and episodic migraine patients were randomized in blinded-fashion 1:1:1 into one of three treatment groups – a quarterly dosing regimen, a monthly dosing regimen or matching placebo. An open-label extension of three months (weeks 13-24) followed the placebo-controlled portion of the study.

About Migraine

IR Contacts	**Global**	Kevin C. Mannix	(215) 591-8912
PR Contacts	**US**	Doris Saltkill	(+1) 816-391-8881
	Europe	Fiona Cohen	(31) 6 2008 2545
	Israel	Yonatan Beker	972 (54) 888 5898

Migraine is a disabling neurological disease characterized by severe head pain, nausea and vomiting.i With more than 1 billion people affected worldwide, migraine is the third most prevalent disease in the world.ii

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

Teva 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 regarding Fremanezumab (commercialized as AJOVY®), 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:

- *the uncertainty of commercial success of AJOVY®;*
- *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*

IR Contacts	**Global**	Kevin C. Mannix	(215) 591-8912
PR Contacts	**US**	Doris Saltkill	(+1) 816-391-8881
	Europe	Fiona Cohen	(31) 6 2008 2545
	Israel	Yonatan Beker	972 (54) 888 5898

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.*

▼ Adverse events should be reported.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events.

Reporting forms and information can be found at https:// www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Teva – please refer to local numbers.

###

[i] Migraine Research Foundation. Migraine Facts. https://migraineresearchfoundation.org/about-migraine/migraine-facts/. Accessed November 2018.
[ii] Migraine Trust. Facts and Figures. https://www.migrainetrust.org/about-migraine/migraine-what-is-it/facts-figures/. Accessed November 2018.

IR Contacts	**Global**	Kevin C. Mannix	(215) 591-8912
PR Contacts	**US**	Doris Saltkill	(+1) 816-391-8881
	Europe	Fiona Cohen	(31) 6 2008 2545
	Israel	Yonatan Beker	972 (54) 888 5898