



Press Release

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## Teva Announces Publication of ARM-TD Study Results in *Neurology*<sup>®</sup> for the Investigational Use of Deutetrabenazine in Tardive Dyskinesia

**Jerusalem, April 27, 2017** – Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today announced the publication of results from the Phase II/III study ARM-TD (**A**im to **R**educe **M**ovements in **T**ardive **D**yskinesia) in *Neurology*<sup>®</sup>, the medical journal of the American Academy of Neurology. The ARM-TD study evaluated the safety and efficacy of the investigational use of deutetrabenazine (SD-809) compared to placebo in the treatment of moderate to severe tardive dyskinesia (TD).

“Tardive dyskinesia is a chronic and debilitating condition that affects patients who are already suffering from significant primary psychiatric illnesses,” said Michael Hayden, M.D., Ph.D., President of Global R&D and Chief Scientific Officer at Teva. “We are pleased to share this publication with the scientific community.”

[Randomized controlled trial of deutetrabenazine for tardive dyskinesia](#) was published online ahead of print in *Neurology*<sup>®</sup>. The ARM-TD study and publication was led by Principal Investigators Hubert Fernandez, M.D., Professor of Neurology at the Center for Neurological Restoration at the Cleveland Clinic and Karen E. Anderson, M.D., Associate Professor of Psychiatry & Neurology at Georgetown MedStar University Hospital.

### About the ARM-TD Study

The ARM-TD study was a 1:1 randomized, multi-center, double-blind, placebo-controlled, parallel-group study of 117 patients in the United States and Europe (104 patients completed the study) with moderate to severe tardive dyskinesia. Enrolled patients received either deutetrabenazine or placebo, which was titrated to optimal dosage over the course of six weeks, and then administered at that dose for another six weeks for a total treatment of 12 weeks.

The objectives of the study were to evaluate the efficacy of deutetrabenazine in reducing the severity of abnormal involuntary movements associated with tardive dyskinesia and to evaluate the safety and tolerability of titration and maintenance therapy with deutetrabenazine in subjects with drug-induced tardive dyskinesia.

### About Tardive Dyskinesia

Tardive dyskinesia, a condition for which there are no approved therapies in the United States, is a movement disorder characterized by repetitive and uncontrollable movements of the tongue, lips, face, trunk and extremities. The often debilitating disorder affects about 500,000 people in the United States and is usually a result of treatment with widely used medications for psychiatric conditions such as schizophrenia and bipolar disorder.

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### About Deutetrabenazine

Deutetrabenazine, an investigational treatment for tardive dyskinesia, is an oral, small molecule inhibitor of vesicular monoamine 2 transporter, or VMAT2, that is designed to regulate the levels of a specific neurotransmitter, dopamine, in the brain. Deutetrabenazine is approved in the United States for the treatment of chorea associated with Huntington's disease

### About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by approximately 200 million patients in 100 markets every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,800 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has the world-leading innovative treatment for multiple sclerosis as well as late-stage development programs for other disorders of the central nervous system, including movement disorders, migraine, pain and neurodegenerative conditions, as well as a broad portfolio of respiratory products. Teva is leveraging its generics and specialty capabilities in order to seek new ways of addressing unmet patient needs by combining drug development with devices, services and technologies. Teva's net revenues in 2016 were \$21.9 billion. For more information, visit [www.tevapharm.com](http://www.tevapharm.com).

### Cautionary Statements Regarding Forward-Looking Information:

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 generics medicines business, including: that we are substantially more dependent on this business, with its significant attendant risks, following our acquisition of Actavis Generics; our ability to realize the anticipated benefits of the acquisition (and any delay in realizing those benefits) or difficulties in integrating Actavis Generics; 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 generic products, both from competing products and as a result of increased governmental pricing pressures; and our ability to take advantage of high-value biosimilar opportunities;
- our specialty medicines business, including: competition for our specialty products, especially Copaxone®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; our ability to market Austedo™ successfully and realize its potential, our ability to achieve expected results from investments in our product pipeline; competition from companies with greater resources and capabilities; and the effectiveness of our patents and other measures to protect our intellectual property rights;
- our substantially increased indebtedness and significantly decreased cash on hand, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, and may result in a downgrade of our credit ratings;

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- our business and operations in general, including: uncertainties relating to our recent senior management changes; our ability to develop and commercialize additional pharmaceutical products; 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 information technology systems or breaches of our data security; the failure to recruit or retain key personnel, including those who joined us as part of the Actavis Generics acquisition; the restructuring of our manufacturing network, including potential related labor unrest; the impact of continuing consolidation of our distributors and customers; variations in patent laws that may adversely affect our ability to manufacture our products; adverse effects of political or economic instability, major hostilities or terrorism on our significant worldwide operations; and our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions;
- 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; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; governmental investigations into sales and marketing practices; potential liability for sales of generic products prior to a final resolution of outstanding patent litigation; 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 risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; the significant increase in our intangible assets, which may result in additional substantial impairment charges; potentially 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 20-F for the year ended December 31, 2016 (“Annual Report”) and in our other filings with the U.S. Securities and Exchange Commission (the “SEC”). 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 advised to consult any additional disclosures we make in our reports to the SEC on Form 6-K, as well as the cautionary discussion of risks and uncertainties under “Risk Factors” in our Annual Report. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those listed could also materially and adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

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**טבע מודיעה על פרסום תוצאות מחקר ARM-TD בכתב העת *Neurology*<sup>®</sup>, מחקר העוסק בשימוש נסיוני ב- Deutetrabenazine עבור דיסקינזיה מאוחרת**

ירושלים, 27 באפריל, 2017 – טבע תעשיות פרמצבטיות בע"מ (NYSE and TASE: TEVA) הודיעה היום על פרסום תוצאות מתוך מחקר בשלב 3/2 המכונה ARM-TD (Aim to Reduce Movements in Tardive Dyskinesia) בכתב העת *Neurology*<sup>®</sup>, כתב העת של האגודה האמריקאית לנירולוגיה. מחקר ARM-TD בחן את הבטיחות והיעילות של השימוש הנסיוני ב-deutetrabenazine (SD-809) בהשוואה לפלצבו לטיפול בדיסקינזיה מאוחרת ברמה בינונית עד חמורה.

"דיסקינזיה מאוחרת היא תופעה כרונית ומגבילה המשפיעה על מטופלים אשר כבר סובלים ממחלות פסיכיאטריות משמעותיות," אמר ד"ר מייקל היידן, נשיא המו"פ הגלובלי והמדען הראשי של טבע. "אנו שמחים לחלוק את הפרסום הזה עם הקהילה המדעית."

[ניסוי רנדומלי מבוקר של deutetrabenazine עבור דיסקינזיה מאוחרת](#) פורסם באתר כתב העת *Neurology*<sup>®</sup> טרם פרסומו בדפוס. מחקר ARM-TD ופרסומו הובלו על ידי החוקרים הראשיים ד"ר היוברט פרננדז, פרופסור לנירולוגיה במחקר השיקום הנירולוגי של ה-Cleveland Clinic וד"ר קארן א. אנדרסון, פרופסורית חברה לפסיכיאטריה ונירולוגיה בבית החולים האוניברסיטאי MedStar בג'ורג'טאון.

#### אודות מחקר ARM-TD

מחקר ARM-TD היה מחקר אקראי ביחס של 1:1, כפול סמיות, מבוקר פלצבו, של קבוצות מקבילות, בקרב 117 מטופלים מכל העולם (מתוכם 104 מטופלים השלימו את הניסוי) הסובלים מדיסקינזיה מאוחרת ברמה בינונית עד חמורה. המטופלים שנרשמו לניסוי קיבלו deutetrabenazine או פלצבו, במנות גדלות בהדרגה עד למינון האופטימלי במשך ששה שבועות, ולאחר מכן קיבלו המשך טיפול במינון זה למשך ששה שבועות נוספים, כך שמשך הטיפול הכולל היה 12 שבועות.

יעדי המחקר היו להעריך את היעילות של deutetrabenazine בהפחתת החומרה של תנועות בלתי רצונית חריגות הנלוות לדיסקינזיה מאוחרת, ואת הבטיחות והסבילות של תהליך הטיטרציה (הגברת מינון הדרגתית) והטיפול המשמר ב-deutetrabenazine בקרב מטופלים עם דיסקינזיה מאוחרת הנובעת משימוש בתרופות.

#### אודות דיסקינזיה מאוחרת

דיסקינזיה מאוחרת, מחלה שעבורה לא קיימים טיפולים מאושרים בארה"ב, היא הפרעת תנועה המאופיינת בתנועות חוזרות ובלתי נשלטות של הלשון, השפתיים, הפנים, מרכז הגוף והגפיים. המחלה, הפוגעת לעתים תכופות בתפקוד, משפיעה על כ- 500,000 איש בארצות הברית, ונובעת בדרך כלל משימוש בתרופות נפוצות לטיפול בבעיות פסיכיאטריות כגון סכיזופרניה והפרעה דו-קוטבית.

#### אודות Deutetrabenazine

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vesicular Deutetrabenazine, טיפול נסיוני לדיסקינזיה מאוחרת, הוא מולקולה אוראלית המהווה חסם של VMAT2 monoamine 2 transporter (VMAT2) והמיועד לווט את רמות הדופמין במוח. Deutetrabenazine מאושר בארה"ב לטיפול בכוריאה (מחולית) הנלווית למחלת הנטינגטון.

### אודות טבע

טבע תעשיות פרמצבטיות בע"מ (NYSE & TASE: TEVA) היא חברת תרופות גלובלית המספקת פתרונות בריאות ממוקדי-מטופל באיכות גבוהה המשמשים כ-200 מיליוני מטופלים ב-100 שווקים מדי יום. טבע, שבסיסה בישראל, היא יצרנית התרופות הגנריות הגדולה בעולם, הממנפת את צבר מוצריה הכולל יותר מ-1,800 מולקולות לייצור מגוון רחב של מוצרים גנריים ברוב התחומים הטיפולים. בתחום התרופות הייחודיות, לטבע יש את הטיפול החדשני המוביל בעולם לטיפול בטרשת נפוצה וכן תכניות מחקר מתקדמות למחלות אחרות של מערכת העצבים המרכזית, כולל הפרעות תנועה, מיגרנה, כאב ותופעות ניווניות, וכן פורטפוליו מוצרים רחב בתחום הנשימה. טבע ממנפת את יכולתיה בגנריקה ובתרופות הייחודיות במטרה לחפש דרכים חדשות לענות על צרכי המטופלים, וזאת על ידי שילוב פיתוח תרופות יחד עם פיתוח תכשירים, שירותים וטכנולוגיות. הכנסות טבע בשנת 2016 הסתכמו ב-\$21.9 מיליארד. למידע נוסף על החברה, בקרו באתר [www.tevapharm.com](http://www.tevapharm.com)

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- our substantially increased indebtedness and significantly decreased cash on hand, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, and may result in a downgrade of our credit ratings;
- our business and operations in general, including: uncertainties relating to our recent senior management changes; our ability to develop and commercialize additional pharmaceutical products; manufacturing or quality

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