



Press Release

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## Teva Announces Publication of AIM-TD Study Results in *The Lancet Psychiatry* for the Investigational Use of Deutetrabenazine in Tardive Dyskinesia

**Jerusalem, June 29, 2017** – Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today announced the publication of results from the Phase III study, AIM-TD (**A**ddressing **I**nvolutionary **M**ovements in **T**ardive **D**yskinesia), in the medical journal, *The Lancet Psychiatry*. The AIM-TD study evaluated the safety, efficacy and tolerability of the investigational use of fixed-dose deutetrabenazine (SD-809) compared to placebo for the treatment of tardive dyskinesia (TD).

“TD is a chronic condition that affects patients who are suffering from primary psychiatric illnesses, which are already debilitating and can be socially isolating,” 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 psychiatry and movement disorder community, who play a critical role in the identification and treatment of hyperkinetic movement disorders like TD.”

[Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia \(AIM-TD\): a double-blind, randomised, placebo-controlled, phase 3 trial](#) was published online ahead of print in *The Lancet Psychiatry*. The AIM-TD study and publication was led by Principal Investigators Karen E. Anderson, M.D., Associate Professor of Psychiatry & Neurology at Georgetown MedStar University Hospital, and Hubert Fernandez, M.D., Professor of Neurology at the Center for Neurological Restoration at the Cleveland Clinic.

### About the AIM-TD Study

AIM-TD was a Phase III, randomized, double-blind, placebo-controlled, parallel group, fixed-dose study that evaluated 222 male and female adults with moderate to severe TD. All patients had a total motor Abnormal Involuntary Movement Scale (AIMS)  $\geq 6$  at screening and were randomized at baseline in a 1:1:1:1 ratio to receive one of three fixed-dose regimens of deutetrabenazine (12 mg/day, 24 mg/day, or 36 mg/day) or placebo. Patients underwent dose escalation during the initial 4 weeks, followed by an 8-week maintenance period and a 1-week washout.

### About Tardive Dyskinesia

Tardive dyskinesia 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 or the gastrointestinal agent, metoclopramide.

### 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

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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 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 deutetrabenazine, 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:*

- *challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals;*
- *our specialty medicines business, including: competition for our specialty products, especially Copaxone<sup>®</sup>, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; 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 business and operations in general, including: 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 or third party information technology systems or breaches of our data security; the restructuring of our manufacturing network, including potential related labor unrest; the impact of continuing consolidation of our distributors and customers; and variations in patent laws that may adversely affect our ability to manufacture our products;*
- *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*

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*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;*

*and other factors discussed in our Annual Report on Form 20-F for the year ended December 31, 2016 (“Annual Report”), including in the section captioned “Risk Factors,” and in our other filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov) and [www.tevapharm.com](http://www.tevapharm.com). 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.*

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**טבע מודיעה על פרסום תוצאות מחקר AIM-TD בכתב העת *The Lancet Psychiatry*, מחקר העוסק בשימוש נסיוני ב-Deutetrabenazine עבור דיסקינזיה מאוחרת**

ירושלים, 29 ביוני, 2017 – טבע תעשיות פרמצבטיות בע"מ (NYSE and TASE: TEVA) הודיעה היום על פרסום תוצאות מתוך מחקר בשלב 3 המכונה AIM-TD (Addressing Involuntary Movements in Tardive Dyskinesia) בכתב העת הרפואי *The Lancet Psychiatry*. מחקר AIM-TD בחן את הבטיחות, היעילות והסבילות של השימוש הנסיוני ב-Deutetrabenazine (SD-809) במינון קבוע, בהשוואה לפלצבו לטיפול בדיסקינזיה מאוחרת.

"דיסקינזיה מאוחרת היא תופעה כרונית המשפיעה על מטופלים הסובלים ממחלות פסיכיאטריות משמעותיות, הגורמות למוגבלויות ואף לבידוד חברתי" אמר ד"ר מייקל היידן, נשיא המו"פ הגלובלי והמדען הראשי של טבע. "אנו שמחים לחלוק את הפרסום הזה עם הקהילה הפסיכיאטרית וקהילת הפרעות התנועה, המשחקות תפקיד קריטי בזיהוי וטיפול של הפרעות תנועה היפר קינטיות כמו דיסקינזיה מאוחרת."

המאמר

[Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia \(AIM-TD\): a double-blind, randomised, placebo-controlled, phase 3 trial](#)

פורסם ברשת טרם פרסומו בדפוס בכתב העת *The Lancet Psychiatry*. המחקר והמאמר הובלו על ידי החוקרים הראשיים ד"ר קארן אנדרסון, פרופסורית עמיתה לפסיכיאטריה ונירולוגיה בבית החולים האוניברסיטאי מדסטאר בג'ורג'טאון, וד"ר היוברט פרננדז, פרופסור לנירולוגיה במרכז לשיקום נירולוגי בקליבלנד קליניק.

### אודות מחקר AIM-TD

AIM-TD היה מחקר שלב 3 אקראי, כפול סמיות, מבוקר-פלצבו, שנערך בקבוצות מקבילות עם מינונים קבועים וכלל 288 נשים וגברים עם דיסקינזיה מאוחרת ברמה בינונית עד חמורה. כל המטופלים הראו דירוג מוטורי כללי של  $AIMS \geq 6$  בשלב הסינון, וחולקו לקבוצות אקראיות בנקודת ההתחלה ביחס של 1:1:1 על מנת לקבל אחד משלושה מינונים קבועים של Deutetrabenazine (12 מ"ג ליום, 24 מ"ג ליום, 36 מ"ג ליום) או פלצבו. המטופלים קיבלו מינונים הולכים וגדלים במהלך 4 השבועות הראשונים לניסוי, ואחריהם קיבלו מינון קבוע בטיפול התחזוקתי שנמשך 8 שבועות והפסיקו את נטילת התרופה במשך שבוע אחד.

### 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.

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## אודות Deutetrabenazine

Deutetrabenazine, טיפול נסיוני לדיסקינזיה מאוחרת, הוא מולקולה אוראלית המהווה חסם של vesicular monoamine 2 transporter (VMAT2) והמיועד לווסת 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 הגדולה בעולם, הממנפת את צבר מוצריה הכולל יותר מ-1,800 מולקולות לייצור מגוון רחב של מוצרים גנריים ברוב התחומים הטיפוליים. 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 יכולותיה 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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