



## Teva Comments on Anticipated At-Risk U.S. Launch of Generic Glatiramer Acetate 40mg/mL and Launch of Generic Glatiramer Acetate 20mg/mL

**Jerusalem, October 4, 2017** – Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today commented that any launch by Mylan of a generic version of COPAXONE<sup>®</sup> 40mg/ml (glatiramer acetate) prior to final resolution of the pending patent appeals and other patent litigation should be considered an “at-risk” launch, which could subject Mylan to significant damages among other remedies. Additionally, Mylan also announced approval of a generic glatiramer acetate 20mg/mL.

“We have planned for the eventual introduction of a generic competitor to glatiramer acetate,” said Dr. Yitzhak Peterburg, Teva’s Interim President and CEO. “We remain confident in patient and physician loyalty to Teva’s COPAXONE<sup>®</sup> due to its recognized efficacy, safety and tolerability profile, and we will continue to promote and support the product. As we are closing the third quarter, it is too soon to officially comment on any change to our full year business outlook.”

Two appeals will be argued before a single panel of judges of the U.S. Court of Appeals for the Federal Circuit. In the first case, Teva is appealing the December 2016 *inter partes* review decisions of the Patent Trial Appeal Board that found all of the claims of three COPAXONE<sup>®</sup> patents to be unpatentable. In the second case, Teva is appealing the January 2017 decision of the U.S. District Court for the District of Delaware, which declared certain claims of four COPAXONE<sup>®</sup> patents invalid. The two appeals have been fully briefed and await the scheduling of oral arguments. In additional litigation, Teva brought suit against five Abbreviated New Drug Application (ANDA) filers, including Mylan, for infringement of a patent covering a manufacturing process for glatiramer acetate product.

Due to the anticipated launch of another generic 20mg glatiramer acetate product and the anticipated launch of a first generic 40mg glatiramer acetate product, Teva’s early assessment of the impact of these launches to its earnings for the fourth quarter ended December 31, 2017 is that it could be affected by at least \$0.25 cents per share. These conditions are subject to change based on the discount; adoption rate; and other factors of the competitive products. Teva will provide additional details on its 3<sup>rd</sup> Quarter Earnings Conference Call on November 2, 2017.

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**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 over 60 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**

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- *Copaxone<sup>®</sup>, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives and the effectiveness of our patents and other measures to protect its intellectual property rights;*
- *our specialty medicines business, including: our ability to achieve expected results from investments in our product pipeline; competition for our specialty products including competition from companies with greater resources and capabilities; and our ability to protect our intellectual property rights;*
- *our generics medicines business, including: that we are substantially more dependent on this business, with its significant attendant risks, following our acquisition of Allergan plc's worldwide generic pharmaceuticals business ("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;*

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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 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, 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; our ability to consummate dispositions on terms acceptable to us; 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 and economic 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”), 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 מתייחסת להשקה בסיכון הצפויה לגרסה הגנרית של גלטירמר אצטט 40 מ"ג/מ"ל ולהשקה של גרסה גנרית לגלטירמר אצטט 20 מ"ג/מ"ל**

ירושלים, 4 באוקטובר, 2017 – טבע תעשיות פרמצבטיות בע"מ (NYSE: TEVA) אמרה היום כי כל השקה על ידי מיילן של גרסה גנרית לקופקסון 40 מ"ג/מ"ל (גלטירמר אצטט) לפני החלטה סופית של ערעורי הפטנטים התלויים ועומדים והתדיינות משפטיות אחרות צריכה להיחשב כהשקה "בסיכון", דבר שעלול להשית על מיילן תשלום נזקים משמעותיים כחלק מסעדים נוספים. בנוסף, מיילן הודיעה על קבלת אישור לגרסה גנרית של גלטירמר אצטט 20 מ"ג/מ"ל.

"אנו נערכנו מבעוד מועד להשקה של מתחרה גנרית לגלטירמר אצטט", אמר פרופ' יצחק פטרבורג, נשיא ומנכ"ל טבע הזמני. "אנו ממשיכים לבטוח בנאמנות הרופאים והמטופלים לקופקסון של טבע, הודות לפרופיל היעילות, הבטיחות והסבילות המוכרים, ואנו נמשיך לתמוך במוצר ולקדמו. בעת שאנו סוגרים את הרבעון השלישי, זה מוקדם מדי להתייחס באופן רשמי לכל לשינוי לתחזית העסקית המלאה שלנו".

שני ערעורים יידונו בפני פאנל אחד של שופטים בבית הדין הפדרלי לערעורים. במקרה הראשון, טבע מערערת על החלטות ועדת הביקורת לפטנטים מחודש דצמבר 2016, אשר קבעו כי כל הטענות לשלושה פטנטים עבור קופקסון אינן תקפות. במקרה השני, טבע ערערה על החלטתו של בית המשפט המחוזי של ארה"ב למחוז דלאוור מינואר 2017, שהכריזה כי בקשות מסוימות לגבי ארבעה פטנטים של קופקסון אינן תקפות. התיקים עבור שתי העתירות מולאו והן ממתנות לתזמון הטיעונים בעל פה. במסגרת התדיינות משפטית נוספת, טבע תובעת חמש חברות אשר הגישו בקשות מקוצרות לאישור תרופה חדשה (ANDA), לרבות מיילן, בגין הפרת פטנט המכסה תהליך ייצור של מוצר גלטירמר אצטט.

בשל ההשקה הצפויה של מוצר נוסף לגלטירמר אצטט 20 מ"ג וההשקה הצפויה של מוצר גלטירמר אצטט 40 מ"ג גנרי ראשון, התחזית המוקדמת של טבע בדבר ההשפעה של השקות אלו על רווחיה לרבעון הרביעי שיתיים ב-31 בדצמבר 2017 עלולה להיות מושפעת בכ-25 סנט למניה. תנאים אלה צפויים לשינוי בהתבסס על הנחות, שיעור אימוץ ופקטורים אחרים בנוגע למוצאים המתחרים. טבע תספק פרטים נוספים בשיחת הוועידה לרבעון השלישי ב-2 בנובמבר 2017.

### 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 ביותר מ-60 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

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Press Release

for  
immediate  
release

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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