



Teva Pharmaceutical Industries Ltd.

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**FOR IMMEDIATE RELEASE**

**TEVA AND ALPHARMA ENTER INTO AGREEMENT RELATING TO  
GABAPENTIN**

**Jerusalem, Israel, April 28, 2004** – Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has entered into an agreement with Alpharma Inc. (NYSE:ALO) pertaining to pending Abbreviated New Drug Applications (ANDAs) for gabapentin 600 mg and 800 mg tablets, and gabapentin 100 mg, 300 mg and 400 mg capsules, the bioequivalent versions of Pfizer's Neurontin® Tablets and Neurontin® Capsules. Neurontin® Tablets and Neurontin® Capsules had U.S. sales of over \$2 billion for the twelve-month period ended December 31, 2003 according to IMS.

Alpharma holds a final ANDA approval for its gabapentin capsules and is awaiting final ANDA approval for the tablets. Teva Pharmaceuticals USA, Inc. ("Teva USA") currently holds tentative approvals for both the tablets and the capsules. The parties believe that the Alpharma ANDAs for the products are entitled, under the Hatch-Waxman Act, to a 180-day period of marketing exclusivity, although another generic manufacturer has challenged these rights in litigation pending in a U.S. District Court. Patent litigation is pending with Pfizer on these products.

Under the terms of the agreement, Alpharma will permit Teva USA to launch its gabapentin within Alpharma's exclusivity period, and Teva will make certain payments, based on Teva USA's sales, to Alpharma relating to the period of exclusivity. In addition, the parties have agreed to certain risk sharing arrangements relating to patent litigation risks regarding a gabapentin launch.

Mr. Israel Makov, President and CEO of Teva, commented: "We are pleased to enter into this agreement with Alpharma. We believe that this agreement will facilitate the introduction of the generic version of this important product and thereby significantly reduce its cost to the U.S. consumer."

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 30 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva's sales are in North America and Europe.

*Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, including its recent acquisition of Sico Inc., the availability of product liability coverage in the current insurance market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.*



## טבע מודיעה כי חתמה על הסכם עם חברת ALPHARMA בנוגע ל- Gabapentin

טבע מודיעה כי חתמה על הסכם עם חברת (NYSE:ALO) Alpharma Inc. הנוגע להשקת טבליות Gabapentin במינונים של 600 מ"ג ו- 800 מ"ג וכמוסות Gabapentin במינונים של 100 מ"ג, 300 מ"ג ו- 400 מ"ג אשר בקשות עבורן ממתניות לאישורה של רשות המזון והתרופות האמריקאית (FDA). Gabapentin הוא הגירסה הגנרית של Neurontin® של חברת Pfizer. על-פי נתוני IMS, המכירות בארה"ב של המוצר המקורי, בטבליות ובכמוסות, היו מעל ל- 2 מליארד \$ בשנת 2003.

Alpharma קיבלה אישור סופי לכמוסות Gabapentin וממתניה לאישור סופי מה- FDA, לטבליות. לטבע ארה"ב אישור מותנה הן לכמוסות והן לטבליות. הצדדים מאמינים כי Alpharma זכאית לתקופת בלעדיות של 180 יום עבור מוצרים אלה במסגרת חוק Hatch-Waxman, זאת, למרות שחברה גנרית אחרת איתגרה זכויות אלה והנושא ממתין לדיון בבית המשפט המחוזי בארה"ב. ההתדיינות המשפטית עם חברת Pfizer, לגבי הפטנט על מוצרים אלה, תלויה ועומדת.

על-פי תנאי ההסכם, Alpharma תתיר לטבע ארה"ב להשיק את המוצרים של טבע במהלך תקופת הבלעדיות של Alpharma וטבע תבצע תשלומים מסויימים ל- Alpharma שיתייחסו למכירות של טבע בארה"ב, במהלך תקופת הבלעדיות של- Alpharma. בנוסף הסכימו הצדדים להסדרים מסויימים לגבי חלוקת הסיכון ביניהן בנוגע להשקת Gabapentin במהלך ההתדיינות המשפטית.

ישראל מקוב, מנכ"ל טבע אמר: "אנו שמחים על חתימת ההסכם עם Alpharma. אנו מאמינים כי הסכם זה יאפשר השקת הגירסאות הגנריות של מוצר חשוב זה, מהלך שיקטין באופן משמעותי עלויותיו לתועלת הצרכן האמריקאי."

טבע תעשיות פרמצבטיות בע"מ הינה חברה גלובלית שבסיסה בישראל ואחת מ- 30 החברות הפרמצבטיות המובילות בעולם. טבע, המתמחה בייצור תרופות גנריות וייחודיות ובייצור חומרים פעילים לתעשייה הפרמצבטית, הינה אחת מהמובילות בעולם בתחום הגנריקה. לטבע אתרי ייצור, מחקר, שיווק והפצה בישראל, בצפון אמריקה ובאירופה. קרוב ל- 90% ממכירותיה של הקבוצה הן לצפון אמריקה ואירופה.

"להלן הסעיף הידוע בארה"ב בשם "Safe Harbor" ואשר מטרתו להגן על החברה, עפ"י הדין האמריקאי, בכל הקשור לנתונים שיש להם משמעות של תחזית ואשר כתוצאה מכך חשופים לסיכונים ואי ודאות:

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