



Teva Completes Acquisition of Labrys: Opens Door to a Strong and Novel Migraine Prevention and Treatment Franchise within its CNS Portfolio

JERUSALEM – July 21, 2014: Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) today announced the successful completion of the acquisition of Labrys.

The acquisition of Labrys brings to Teva LBR-101, a fully humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP), which is currently in Phase IIb clinical trials for prevention of chronic and episodic migraine. Teva's acquisition of LBR-101 complements the recent acquisition of ZECUITY®, a novel iontophoretic patch that delivers sumatriptan via the skin for the acute treatment of migraine, and positions Teva to compete for leadership in the treatment and prevention of migraine.

Additionally, the growing migraine franchise forms part of a strategic expansion of Teva's overall CNS portfolio, in addition to a number of products in development for a broad range of pain states and in particular a large development program in the field of potential abuse deterrent opioids.

"We are pleased to finalize this acquisition. It's an exciting opportunity to develop a much needed treatment option for people suffering from the impact of chronic and episodic migraine. The CGRP pathway is scientifically robust, the molecule has the right specifications to deliver on its clinical promise and the patient population is both large and underserved. This could make a real and meaningful difference to patients' lives" said Michael Hayden, Teva's President of Global R&D and Chief Scientific Officer.

About LBR-101

LBR-101 (formerly RN-307) is a monoclonal antibody that binds to calcitonin gene-related peptide (CGRP), a well-validated target in migraine. It is currently in Phase IIb clinical trials for prevention of episodic and chronic migraine. LBR-101, originally discovered by Rinat Neuroscience (bought by Pfizer in 2006), was acquired by Labrys from Pfizer in 2012. LBR-101 has successfully completed five Phase I trials with 94 healthy volunteers dosed with active drug. Results were [published in Cephalalgia](#), the official journal of the International Headache Society, in December 2013, and presented at the 2014 annual meeting of the American Academy of Neurology. A sixth Phase 1 study (bridging study) tested IV and subcutaneous doses (24 participants received active medication). Both intravenous and subcutaneous administrations were well tolerated. LBR-101 exhibited a long terminal half-life which supports once-monthly subcutaneous dosing. Most treatment-related adverse events were mild, transient and resolved spontaneously. The maximum tolerated dose has not been identified. LBR-101 was not associated with any clinically relevant patterns of change in vital signs, ECG parameters, or laboratory findings.

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Proof of efficacy has been observed for several small-molecule CGRP antagonists in the symptomatic (acute) relief of migraine. However, liver toxicity or formulation difficulties have limited their use in migraine prophylaxis. Chronic migraine is characterized by headaches on at least 15 days per month and high frequency episodic migraine shares many similarities with chronic migraine. Patients with this condition are at a high risk of transformation to chronic migraine, and have similar unmet needs due to a paucity of currently approved preventive medications. These preventive medications require daily use, are not effective in a large percentage of patients, and are commonly associated with adverse events. Consequently, prophylactic treatment of episodic and chronic migraine continues to present considerable challenges, and there remains a significant medical need for new, safe and effective migraine prophylactic treatment options.

About Teva

Teva Pharmaceutical Industries Ltd. is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's leading generic drug maker, with a global product portfolio of more than 1,000 molecules and a direct presence in approximately 60 countries. Teva's specialty medicine business focuses on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 45,000 people around the world and reached \$20.3 billion in net revenues in 2013.

Safe Harbor Statement under the U.S. Private Securities Litigation Reform Act of 1995:

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executive and managerial talent; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; the impact of continuing consolidation of our distributors and customers; significant impairment charges relating to intangible assets and goodwill; potentially significant increases in tax liabilities; 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; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2013 and in our 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 we assume no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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טבע השלימה את רכישת Labrys: פותחת את הדלת לבניית תחום חדשני וחזק למניעה וטיפול במיגרנה במסגרת סל תרופות מערכת העצבים המרכזית של החברה

ירושלים, 21 ביולי, 2014 – טבע תעשיות פרמצבטיות בע"מ (NYSE: TEVA) הודיעה היום כי היא השלימה בהצלחה את רכישת לבריס (Labrys).

רכישת לבריס מביאה לטבע את LBR-101, נוגדן חד שבטי מואנש באופן מוחלט אשר נקשר לקליטונין פפטיד של הגן (CGRP) ואשר נמצא כרגע במחקרים קליניים בשלב IIb למניעת מיגרנות כרוניות וארעיות. הרכישה של LBR-101 מוסיפה לרכישה של Zecuity®, מדבקה איונטופרית חדשנית המוליכה סומטריפטן אל העור לשם טיפול אקוטי במיגרנה, וממצבת את טבע להתמודדות על ההובלה בטיפול ומניעה של מיגרנה.

בנוסף, תחום המיגרנה הגדל של טבע מהווה חלק מהרחבה אסטרטגית של תחום מערכת העצבים המרכזית בחברה בכללותו, הכולל מספר מוצרים בפיתוח לטיפול בטווח רחב של מצבי כאב, ובמיוחד פיתוח רחב היקף במסגרת תכנית המתמקדת במשככי כאבים המרתיעים שימוש לא נאות.

"אנחנו מרוצים מהשלמת הרכישה. זוהי הזדמנות מיוחדת לפתח אופציית טיפול נחוצה במיוחד עבור אנשים הסובלים מההשפעות של מיגרנה כרונית וארעית. נתיב ה-CGRP הינו חזק מדעית, הנוגדן נראה כרלוונטי רפואית ואוכלוסיית המטופלים הנה גדולה וללא מענה מתאים. יש כאן פוטנציאל להביא לשינוי אמיתי ומשמעותי בחיי מטופלים," אמר מייקל היידן, נשיא מחקר ופיתוח והמדען הראשי של טבע.

אודות LBR-101

LBR-101 (לשעבר RN-307) הוא נוגדן חד שבטי הנקשר לקליטונין פפטיד של הגן (CGRP), יעד בעל תוקף רב במיגרנות. הנוגדן נמצא כרגע במחקרים קליניים בשלב IIb למניעת מיגרנות כרוניות וארעיות. LBR-101 התגלה ופותח לראשונה על ידי חברת התרופות רינת, שנרכשה על ידי פייזר בשנת 2006. LBR-101 עבר את מחקרי שלב I בהצלחה עם 116 מתנדבים בריאים שקיבלו את התרופה הפעילה. התוצאות [פורסמו ב-Cephalalgia](#), כתב העת הרשמי של אגודת כאב הראש הבינלאומית בדצמבר 2013, והוצגו בפגישה השנתית של האקדמיה האמריקאית לנירולוגיה בשנת 2014. התרופה ניתנה באופן תוך ורידי ובאופן תת עורי ובשני המקרים הטיפול הציג סבילות גבוהה. LBR-101 מפגין זמן מחצית חיים סופני ארוך מה שתומך במינון של פעם בחודש. רוב תופעות הלוואי המיוחסות לטיפול היו קלות, זמניות ונפתרו מעצמן. המינון הנסבל המקסימלי עדיין לא זוהה. לא יוחסו ל-LBR-101 כל תבניות קליניות רלוונטיות של שינוי בסימני החיים, פרמטרים של אק"ג או ממצאי מעבדה.

הוכחות לאפקטיביות נמצאו במספר אנטגוניסטי CGRP בעלי מולקולה קטנה בהקלה סימפטומטית (אקוטית) של המיגרנה. עם זאת, רעילות בכבד או קשיים בפורמולציה הגבילה את השימוש שלהם למניעת מיגרנות. קיימת רק תרופה אחת שאושרה על ידי מנהל התרופות והמזון האמריקאי למניעת

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מיגרנות (onabotulinumtoxin A), עובדה אשר מדגישה את הצורך הרפואי בטיפולים בטוחים ויעילים למניעת מיגרנות. ישנם קווי דמיון רבים בין מיגרנות ארעיות בתדירות גבוהה ובין מיגרנות כרוניות. קיים סיכון גבוה שמטופלים הסובלים ממצב זה יפתחו מיגרנה כרונית, ויש להם צרכים דומים ללא מענה בעקבות המחסור בטיפולים מונעים מאושרים. טיפולים מונעים אלה דורשים שימוש יומי, אינם אפקטיביים בקרב חלק גדול מהמטופלים, ומגיעים בדרך כלל עם תופעות לוואי.

אודות טבע

טבע תעשיות פרמצבטיות בע"מ (NYSE: TEVA) היא חברת תרופות גלובלית המחויבת לפיתוח ולשיווק תרופות באיכות גבוהה בהישג יד בכל מקום בעולם. החברה, שבסיסה בישראל, עוסקת ביצור תרופות גנריות, תרופות ייחודיות וממותגות ובייצור חומרי גלם פעילים לתעשייה הפרמצבטית.

טבע מובילה את שוק התרופות הגנריות העולמי, עם נוכחות ביותר מ-60 מדינות ועם סל תרופות של למעלה מ-1,000 מולקולות הנמכר ביותר מ-100 שווקים. התרופות הייחודיות והממותגות של החברה מתמקדות בתחומי מערכת העצבים המרכזית, האונקולוגיה, הכאב, הנשימה ובריאות האישה, כמו גם בתחום התרופות הביולוגיות. טבע מעסיקה כיום כ-45,000 איש. מכירות החברה הסתכמו בשנת 2013 ב-20.3 מיליארד דולר.

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