Press Release

for immediate release

FDA APPROVES TEVA'S SYNRIBO® (OMACETAXINE MEPESUCCINATE) FOR INJECTION FOR HOME ADMINISTRATION

New Labeling will Offer People Living with Chronic Myeloid Leukemia (CML) More Treatment Flexibility

Jerusalem, May 5, 2014 – Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) today announced that the U.S. Food and Drug Administration (FDA) has approved SYNRIBO® (omacetaxine mepesuccinate) for injection, for subcutaneous use, to include home administration, and also approved a related Medication Guide and Instructions for Use. With this approval, physicians who treat adults with chronic or accelerated phase CML who are no longer responding to, or who could not tolerate, two or more tyrosine kinase inhibitors (TKIs) will now have the option to allow their patients to administer SYNRIBO® therapy at home. Teva is working to finalize a comprehensive specialty pharmacy support program which will help facilitate successful home administration of SYNRIBO® for HCPs, their patients and caregivers. This program is expected to "go live" as early as possible in the second quarter of 2014.

"As we continue to expand our oncology portfolio and services at Teva, the updated labeling for SYNRIBO® demonstrates our commitment to improving the overall experience and lowering barriers to treatment for people living with CML," said Bill Campbell, Vice President and General Manager, Teva Oncology. "Home administration can reduce the number of required doctor office visits for patients being treated with SYNRIBO®, while still maintaining close collaboration with their healthcare provider to manage their treatment regimen."

"It had been necessary for adults living with chronic or accelerated phase CML who are prescribed SYNRIBO® to travel to their doctor's office twice a day for two weeks, which can be extremely burdensome and inconvenient to both patients and their caregivers," said Meir Wetzler, MD, FACP, Chief of the Leukemia Section at Roswell Park Cancer Institute. "Now, physicians can decide if their patients are candidates for self administration, and if so, provide their patients with guidance on how to properly administer reconstituted SYNRIBO® in the home."

"As an oncology nurse practitioner who has treated CML patients for nearly 20 years, I'm thrilled to see this unique therapy become available for home administration," said Sandra Corbin, CRNP at Calvert Hematology and Oncology. "Patients may initially express concern at the thought of self-injecting—but with training and support, most can become skilled at administering the subcutaneous injections."

Indication

SYNRIBO® (omacetaxine mepesuccinate) for Injection, for subcutaneous use, is indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI).

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Important Safety Information

Warnings and Precautions

- Myelosuppression: Patients with chronic phase and accelerated phase CML who used SYNRIBO® experienced severe and fatal myelosuppression including thrombocytopenia, neutropenia, and anemia. Patients with neutropenia are at increased risk for infections, and should be monitored frequently and advised to contact a physician if they have symptoms of infection or fever. Monitor complete blood counts weekly during induction and initial maintenance cycles and every two weeks during later maintenance cycles, as clinically indicated
- Bleeding: SYNRIBO® causes severe thrombocytopenia which increases the risk of hemorrhage. Fatalities from cerebral hemorrhage have occurred. Severe, non-fatal gastrointestinal hemorrhages have also occurred. Monitor platelet counts as part of the complete blood count (CBC) monitoring as recommended. Avoid anticoagulants, aspirin, and non-steroidal anti-inflammatory drugs (NSAIDs) when the platelet count is <50,000/µL as they may increase the risk of bleeding
- Hyperglycemia: SYNRIBO® can induce glucose intolerance. Monitor blood glucose levels frequently, especially in patients with diabetes or risk factors for diabetes. Avoid SYNRIBO® in patients with poorly controlled diabetes mellitus until good glycemic control has been established
- Embryo-Fetal Toxicity: SYNRIBO® can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid becoming pregnant while using SYNRIBO®

Adverse Reactions

- Serious adverse reactions (frequency ≥5%) in chronic phase patients: bone marrow failure, thrombocytopenia, febrile neutropenia, and infections
- Serious adverse reactions (frequency ≥5%) in accelerated phase patients: febrile neutropenia, thrombocytopenia, anemia, diarrhea, and infections
- Most common adverse reactions (frequency ≥20%) in chronic and accelerated phase patients: thrombocytopenia, anemia, neutropenia, diarrhea, nausea, fatigue, asthenia, injection site reaction, pyrexia, infection, and lymphopenia
- You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About CML

Chronic myeloid leukemia (also called chronic myelogenous leukemia) is one of four main types of leukemia and is a cancer of the blood and bone marrow. In CML, part of the DNA from one chromosome (chromosome 9) breaks off and trades places with another chromosome (chromosome 22) called a “translocation”. This forms the Philadelphia chromosome, an abnormal chromosome 22 that contains the BCR-ABL hybrid gene. This hybrid gene leads to over-production of the enzyme tyrosine kinase in the bone marrow, which causes too many stem cells to develop into white blood cells (granulocytes or blasts). The American Cancer Society estimates that in 2014, there will be 5,980 new cases of CML

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diagnosed in the United States, and 810 deaths from the disease. The prevalence of CML has grown significantly since 2001 with the development of new therapies.

About SYNRIBO®

SYNRIBO® is the first protein synthesis inhibitor and was originally granted an accelerated approval by the FDA in October 2012. In February of 2014 the FDA granted SYNRIBO a full approval based on the submission of 24 month update to the safety and efficacy data. While a detailed understanding of how SYNRIBO works has not been fully defined, it has been shown in laboratory studies not including patients, to prevent the production of specific proteins. The proteins affected by SYNRIBO are known as Bcr-Abl and Mcl-1. These are examples of some of the proteins that are produced in higher levels by cancerous CML cells and help drive the disease. As a protein synthesis inhibitor, the way SYNRIBO® is believed to work does not directly depend on Bcr-Abl binding.

For Full Prescribing Information, click here: http://www.synribo.com/pdf/synribo_pi.pdf

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) 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 Medicines businesses focus on CNS, respiratory oncology, pain, 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:

This release contains forward-looking statements, which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our 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 risks relating to: our ability to develop and commercialize additional pharmaceutical products; competition for our innovative products, especially COPAXONE® (including competition from orally-administered alternatives, as well as from potential purported generic equivalents); the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; our potential exposure to product liability claims that are not covered by insurance; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our

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exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; uncertainties related to our recent management changes; the effects of increased leverage and our resulting reliance on access to the capital markets; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; adverse effects of political or economical 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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ה-FDA אישר את Synribo® (Omacetaxine Mepesuccinate) של טבע בזריקה לשימוש ביתי

ההתוויה החדשה תציע לאנשים הסובלים מלוקמיה מיאלואידית כרונית (CML) גמישות נוספת בטיפולים

ירושלים, 5 במאי, 2014 – טבע תעשיות פרמצבטיות בע"מ (NYSE: TEVA) הודיעה היום כי מינהל המזון והתרופות האמריקאי (FDA) אישר את Synribo® (Omacetaxine Mepesuccinate) בזריקה תת-עורית לשימוש ביתי, וכן מדריך תרופות והוראות לשימוש עבור התרופה. הודות לאישור זה, רופאים המטפלים בחולים בגירים בשלב הכרוני או המואץ של לוקמיה מיאלואידית כרונית שאינם מגיבים יותר, או לא מסוגלים לסבול שני מעכבי טירוזין קינאז או יותר, יוכלו לאפשר למטופלים לקבל טיפול ב-Synribo® בביתם. טבע עובדת על סיום תוכנית תמיכה מקיפה בבתי המרקחת עבור תרופות ייחודיות שתעזור ליישם בהצלחה את הטיפול הביתי ב-Synribo® עבור קופות חולים, המטופלים והמטפלים. תוכנית זו צפויה להתחיל לפעול בהקדם האפשרי במהלך הרבעון השני של 2014.

"אנו ממשיכים להרחיב את סל מוצרי ושירותי האונקולוגיה של טבע, וההתוויה המעודכנת של Synribo® מדגימה את המחויבות שלנו לשיפור החוויה הכוללת והסרת המחסומים לטיפול באנשים המתמודדים עם לוקמיה מיאלואידית כרונית," אמר ביל קמפבל, סמנכ"ל ומנהל מחלקת האונקולוגיה של החברה. "הטיפול הביתי צפוי להפחית את תדירות הביקורים אצל הרופא של חולים המטופלים ב-Synribo®, תוך כדי שמירה על שיתוף הפעולה הצמוד עם קופת החולים לניהול משטר הטיפול שלהם."

"עד כה היה זה הכרחי שבגירים המתמודדים עם השלב הכרוני או המואץ של לוקמיה מיאלואידית כרונית וטופלו ב-Synribo® יגיעו לרופא שלהם פעמיים ביום במשך שבועיים, דבר המהווה טרחה ונטל כבדים הן לחולים והן לרופאים," אמר ד"ר מאיר וצלר, ראש מחלקת הלוקמיה במכון רוזוול פארק לסרטן. "כעת, הרופאים יכולים להחליט אם המטופלים שלהם מתאימים לטיפול עצמי, ואם כן, להדריך את המטופלים איך להשתמש ב-Synribo® בבית."

"בתור אחות אונקולוגית המטפלת בחולי לוקמיה מיאלואידית כרונית במשך כמעט 20 שנה, אני נרגשת מכך שטיפול ייחודי זה יהיה עכשיו זמין לשימוש ביתי," אמרקה סנדרה קורבין, אחות מורשית בבית החולים קלברט להמטולוגיה ואונקולוגיה. "המטופלים עשויים להביע חששות בנוגע לרעיון של הזרקה עצמית – אך באמצעות הדרכה ותמיכה, רובם יוכלו ללמוד איך לבצע הזרקות תת-עוריות במיומנות."

התוויה

Synribo® (Omacetaxine Mepesuccinate) בזריקה תת-עורית מותוות לשימוש בקרב בגירים בשלב הכרוני או המואץ של לוקמיה מיאלואידית כרונית עם התנגדות ו\או אי-סבילות לשני מעכבי טירוזין קינאז או יותר.

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אודות לוקמיה מיאלואידית כרונית

לוקמיה מיאלואידית כרונית היא אחת מארבעת סוגי הלוקמיה, וכן מהווה סרטן של הדם ומח העצם. בלוקמיה מסוג זה, חלק מה-DNA של כרומוזום אחד (כרומוזום 9) מתנתק ומחליף מקומות עם כרומוזום אחר (כרומוזום 22) במה שנקרא "טרנסולוקציה". תהליך זו יוצר את כרומוזום פילדלפיה, כרומוזום 22 חריג המכיל את גן ה-BCR-ABL. גן כלאיים זה מוביל לייצור יתר של האנזים טירוזין קינאז במח העצם, מה שגורם ליותר מדי תאי גזע להפוך לתאי דם לבנים (גרנולוציטים). על פי ההערכות של האגודה האמריקאית לסרטן, בשנת 2014 יהיו 5,980 מקרים חדשים של לוקמיה מיאלואידית כרונית בארה"ב, ו-810 מיתות מהמחלה. השכיחות של לוקמיה מיאלואידית כרונית גדלה באופן משמעותי מאת שנת 2001 בועד טיפולים חדשים נמצאים בפיתוח.

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אודות ®Synribo

®Synribo קיבל במקור אישור מזורז מה-FDA באוקטובר 2012 בתור מעכב סינתזת חלבון ראשון עבור לוקמיה מיאלואידית כרונית. בפברואר 2014 ה-FDA העניק ל-Synribo אישור מלא על בסיס עדכון בן 24 חודשים שהוגש לנתוני הבטיחות והאפקטיביות. על אף שעדיין לא הוגדרה הבנה מפורטת ומלאה של איך Synribo עובד, התרופה הפגינה את היכולת למנוע את היווצרותם של חלבונים מסוימים במחקרי מעבדה. החלבונים המושפעים על ידי Synribo ידועים כ-BCR-ABL ו-Mcl-1. אלה הן דוגמאות לכמה מהחלבונים שמיוצרים ברמות גבוהות על ידי תאי CML סרטניים ועוזרים להחרפת המחלה. עקב היותו מעכב סינתזת חלבון, האופן ש-®Synribo עובד אינו תלוי באופן ישיר באיחוי ה-BCR-ABL.

למידע מלא על מתן מרשמים, לחצו כאן: http://www.synribo.com/pdf/synribo_pi.pdf

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-120 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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are not covered by insurance; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; uncertainties related to our recent management changes; the effects of increased leverage and our resulting reliance on access to the capital markets; any failure to recruit or retain executives or other key personnel; adverse effects of political or economical 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 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; the potential for significant 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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