



Press Release

for
immediate
release

TEVA ANNOUNCES ADDITIONAL REGULATORY EXCLUSIVITY FOR TREANDA® (BENDAMUSTINE HCl) FOR INJECTION

Orphan Designation combined with pediatric extension provides regulatory exclusivity through April 2016 for indolent B-cell non-Hodgkin lymphoma indication

Jerusalem, November 27, 2013 – Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug exclusivity for TREANDA through October 2015 for indolent B-cell non-Hodgkin lymphoma (iNHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Orphan status is granted to therapies intended to treat diseases or conditions that affect fewer than 200,000 patients in the United States. With the previously granted six months of pediatric exclusivity for TREANDA, regulatory exclusivity for this indication is now extended through April 2016.

“Since 2008, TREANDA has played a significant role in the treatment of patients with iNHL that has progressed,” said Bill Campbell, Vice President and General Manager, Teva Oncology. “We are pleased the FDA has recognized our commitment to treating patients with this rare form of cancer.”

TREANDA is also indicated for the treatment of patients with chronic lymphocytic leukemia (CLL). TREANDA has orphan drug exclusivity for this indication through March 2015. With the previously granted six months of pediatric exclusivity for TREANDA, regulatory exclusivity for this indication lasts until September 20, 2015.

Net sales for Treanda in the United States through the third quarter of 2013 were \$531 million.

Indications

TREANDA is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL). Efficacy relative to first-line therapies other than chlorambucil has not been established.

TREANDA is indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Important Safety Information

- **Allergic Reactions:** Patients with a known allergic response to bendamustine should not take TREANDA.
- **Serious Side Effects:** TREANDA may cause serious side effects, including low blood cell counts, infections, unexpected responses to TREANDA when placed in your blood, sudden and severe allergic responses, kidney failure due to fast breakdown of cancer cells, other cancers, and leaking of TREANDA out of your vein and into your surrounding skin. Some of these side effects, such as low blood counts, infections, and severe allergic skin responses (when TREANDA was given with allopurinol and other medications known to cause severe allergic skin responses), have caused death. Tell your doctor right away if you have any of these side effects.

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



Press Release

for
immediate
release

- **Changes in Therapy:** Some serious side effects may require changes in therapy, such as lowering the amount of TREANDA given, stopping the use of TREANDA, or waiting longer than expected between doses of TREANDA.
- **Pregnancy:** Women should avoid becoming pregnant while using TREANDA because it may cause fetal harm if you take TREANDA while pregnant.
- **Most Common Side Effects:** The most common non-blood-related side effects associated with TREANDA (occurring in $\geq 15\%$ of patients) are nausea, fatigue, vomiting, diarrhea, fever, constipation, loss of appetite, cough, headache, weight loss, difficulty breathing, rash, and mouth irritation. The most common blood-related side effects associated with TREANDA (frequency $\geq 15\%$) are decreased number of three different types of white blood cells (infection-fighting cells), low red blood cells (oxygen-carrying cells), and low platelets (blood-clotting cells).

For full prescribing information, click here <http://www.treanda.com>.

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 TREANDA (bendamustine HCl) Injection

TREANDA was approved by the FDA for the treatment of chronic lymphocytic leukemia (CLL) in March 2008. Efficacy relative to first line therapies other than chlorambucil has not been established. TREANDA received its second approval in October 2008 for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

TREANDA has a unique chemical structure that is synthesized to combine an alkylating group and a purine-like benzimidazole component. Though the exact mechanism of action of TREANDA remains unknown, bendamustine is active against both quiescent and dividing cells. Preclinical studies suggest that TREANDA may lead to cell death by a process known as apoptosis (programmed cell death) as well as by an alternate cell death pathway which disrupts normal cell division known as mitotic catastrophe (a non-apoptotic pathway).

About Indolent Non-Hodgkin lymphoma (NHL)

Non-Hodgkin lymphoma (NHL) is a disease in which cancer cells form in the lymphatic tissue in the body. Because lymph tissue is found throughout the body, NHL can begin almost anywhere in the body and spread to almost any tissue or organ. There are approximately 60 different types of NHL, which are formed from either B-cells or T-cells. The majority of non-Hodgkin lymphomas (80 to 90 percent) are formed by B-cells. Types of NHL are generally divided into two categories—indolent and aggressive. The American Cancer Society (ACS) estimates that in the U.S., 69,740 people will be diagnosed with NHL and 19,020 will die from the disease in 2013.

Indolent non-Hodgkin lymphomas (iNHL) are slow-growing lymphomas. The median survival of patients with indolent lymphoma is approximately 10 years. Indolent lymphomas are often responsive to therapy but usually relapse. According to the Leukemia and Lymphoma Society, about 40 percent of NHL cases are indolent in the U.S. Patients living with NHL may experience signs and symptoms such as fever, sweating, excessive fatigue and weight loss.

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



Press Release

for
immediate
release

About Chronic Lymphocytic Leukemia (CLL)

Chronic lymphocytic leukemia (CLL) is one of four main types of leukemia. CLL begins with a change to a single white blood cell, or lymphocyte, of the bone marrow. Over time, the CLL cells multiply, replacing normal lymphocytes in the marrow and lymph nodes. As the amount of lymphocytes increases in the blood and bone marrow, there is less room for healthy white and red blood cells as well as platelets, which may result in infection, anemia and bleeding.

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 about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 46,000 people around the world and reached \$20.3 billion in net revenues in 2012.

Teva's 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 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, including our ability to develop, manufacture, market and sell biopharmaceutical products, competition for our innovative medicines, especially Copaxone[®] (including competition from innovative orally-administered alternatives, as well as from potential purported generic equivalents), competition for our generic products (including from other pharmaceutical companies and as a result of increased governmental pricing pressures), competition for our specialty pharmaceutical businesses, our ability to achieve expected results through our specialty, including innovative, R&D efforts, the effectiveness of our patents and other protections for innovative products, decreasing opportunities to obtain U.S. market exclusivity for significant new generic products, our ability to identify, consummate and successfully integrate acquisitions and license products, our ability to reduce operating expenses to the extent and during the timeframe intended by our cost restructuring program, uncertainties relating to the replacement of and transition to a new President & Chief Executive Officer, the effects of increased leverage as a result of recent acquisitions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our potential exposure to product liability claims to the extent not covered by insurance, increased government scrutiny in both the U.S. and Europe of our settlement agreements with brand companies and liabilities arising from class action litigation and other third-party claims relating to such agreements, potential liability for sales of generic medicines prior to a final resolution of outstanding patent litigation, our exposure to currency fluctuations and restrictions as well as

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



Press Release

for
immediate
release

credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, any failures to comply with complex Medicare and Medicaid reporting and payment obligations, governmental investigations into sales and marketing practices ,particularly for our specialty medicines (and our ongoing FCPA investigations and related matters), uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology-based medicines, adverse effects of political or economic instability, corruption, major hostilities or acts of terrorism on our significant worldwide operations, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, any failure to retain key personnel or to attract additional executive and managerial talent, the impact of continuing consolidation of our distributors and customers, variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, the termination or expiration of governmental programs or tax benefits, environmental risks, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2012 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 the Company undertakes no obligation to update or revise any forward looking statement, whether as a result of new information, future events or otherwise.

#

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974

טבע מודיעה על בלעדיות נוספת ל- TREANDA® בהזרקה

מעמד תרופת יתום יחד עם הארכה לטיפול בילדים מעניקים בלעדיות רגולטורית עד סוף אפריל 2016 לטיפול בלימפומה שאינה הודג'קין איטית

ירושלים, 27 בנובמבר, 2013 – טבע תעשיות פרמצבטיות בע"מ (NYSE: TEVA) הודיעה היום כי מנהל התרופות והמזון האמריקאי (FDA) העניק בלעדיות מסוג תרופת יתום ל- TREANDA® עד סוף אוקטובר 2015 לטיפול בלימפומה שאינה הודג'קין איטית (iNHL) שהתדרדרה במהלך או לאחר 6 חודשי טיפול עם Rituximab או טיפול תרופתי המכיל Rituximab. מעמד תרופת יתום מוענק לטיפולים המיועדים לטיפול במחלות או תופעות המשפיעות על פחות מ- 200,000 מטופלים בארה"ב. בשילוב עם בלעדיות לטיפול בילדים אשר נתנה בעבר עבור TREANDA®, הבלעדיות הרגולטורית לטיפול זה הוארכה כעת עד לסוף אפריל 2016.

"מאז 2008, TREANDA® משחקת תפקיד משמעותי בטיפול בחולים הסובלים מלימפומה שאינה הודג'קין איטית (iNHL) שהתדרדרה, אמר ביל קמפל, סגן נשיא ומנהל כללי של טבע אונקולוגיה. "אנחנו מרוצים מכך שה- FDA הכיר במחויבותינו לטפל בחולים הסובלים מסוג נדיר של מחלת הסרטן."

TREANDA® מאושרת לשימוש גם עבור מטופלים הסובלים מלוקמיה לימפוציטים כרונית (CLL). ל- TREANDA® יש מעמד תרופת יתום עבור הטיפול במחלה זו, אשר מעניק לה בלעדיות עד סוף מרץ 2015. בתוספת לבלעדיות של שישה חודשים לטיפול בילדים, טיפול זה זוכה לבלעדיות עד ל- 20 בספטמבר 2015.

מכירותיה נטו של TREANDA® בארה"ב ברבעון השלישי של 2013 הסתכמו ב- \$531 מיליון.

Indications

TREANDA is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL). Efficacy relative to first-line therapies other than chlorambucil has not been established.

TREANDA is indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Important Safety Information

- **Allergic Reactions:** Patients with a known allergic response to bendamustine should not take TREANDA.
- **Serious Side Effects:** TREANDA may cause serious side effects, including low blood cell counts, infections, unexpected responses to TREANDA when placed in your blood, sudden and severe allergic responses, kidney failure due to fast breakdown of cancer cells, other cancers, and leaking of TREANDA out of your vein and into your surrounding skin. Some of these side effects, such as low blood counts, infections, and severe allergic skin responses (when TREANDA was given with

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



Press Release

for
immediate
release

allopurinol and other medications known to cause severe allergic skin responses), have caused death. Tell your doctor right away if you have any of these side effects.

- **Changes in Therapy:** Some serious side effects may require changes in therapy, such as lowering the amount of TREANDA given, stopping the use of TREANDA, or waiting longer than expected between doses of TREANDA.
- **Pregnancy:** Women should avoid becoming pregnant while using TREANDA because it may cause fetal harm if you take TREANDA while pregnant.
- **Most Common Side Effects:** The most common non-blood-related side effects associated with TREANDA (occurring in $\geq 15\%$ of patients) are nausea, fatigue, vomiting, diarrhea, fever, constipation, loss of appetite, cough, headache, weight loss, difficulty breathing, rash, and mouth irritation. The most common blood-related side effects associated with TREANDA (frequency $\geq 15\%$) are decreased number of three different types of white blood cells (infection-fighting cells), low red blood cells (oxygen-carrying cells), and low platelets (blood-clotting cells).

For full prescribing information, click here <http://www.treanda.com>.

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 TREANDA (bendamustine HCl) Injection

TREANDA was approved by the FDA for the treatment of chronic lymphocytic leukemia (CLL) in March 2008. Efficacy relative to first line therapies other than chlorambucil has not been established. TREANDA received its second approval in October 2008 for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

TREANDA has a unique chemical structure that is synthesized to combine an alkylating group and a purine-like benzimidazole component. Though the exact mechanism of action of TREANDA remains unknown, bendamustine is active against both quiescent and dividing cells. Preclinical studies suggest that TREANDA may lead to cell death by a process known as apoptosis (programmed cell death) as well as by an alternate cell death pathway which disrupts normal cell division known as mitotic catastrophe (a non-apoptotic pathway).

About Indolent Non-Hodgkin Lymphoma (NHL)

Non-Hodgkin lymphoma (NHL) is a disease in which cancer cells form in the lymphatic tissue in the body. Because lymph tissue is found throughout the body, NHL can begin almost anywhere in the body and spread to almost any tissue or organ. There are approximately 60 different types of NHL, which are formed from either B-cells or T-cells. The majority of non-Hodgkin lymphomas (80 to 90 percent) are formed by B-cells. Types of NHL are generally divided into two categories—indolent and aggressive. The American Cancer Society (ACS) estimates that in the U.S., 69,740 people will be diagnosed with NHL and 19,020 will die from the disease in 2013.

Indolent non-Hodgkin lymphomas (iNHL) are slow-growing lymphomas. The median survival of patients with indolent lymphoma is approximately 10 years. Indolent lymphomas are often responsive to therapy but usually relapse. According to the Leukemia and Lymphoma Society, about 40 percent of NHL cases are

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



Press Release

for
immediate
release

indolent in the U.S. Patients living with NHL may experience signs and symptoms such as fever, sweating, excessive fatigue and weight loss.

About Chronic Lymphocytic Leukemia (CLL)

Chronic lymphocytic leukemia (CLL) is one of four main types of leukemia. CLL begins with a change to a single white blood cell, or lymphocyte, of the bone marrow. Over time, the CLL cells multiply, replacing normal lymphocytes in the marrow and lymph nodes. As the amount of lymphocytes increases in the blood and bone marrow, there is less room for healthy white and red blood cells as well as platelets, which may result in infection, anemia and bleeding.

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-46,000 איש. מכירות החברה הסתכמו בשנת 2012 ב-20.3 מיליארד דולר.

Teva's 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 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, including our ability to develop, manufacture, market and sell biopharmaceutical products, competition for our innovative medicines, especially Copaxone® (including competition from innovative orally-administered alternatives, as well as from potential purported generic equivalents), competition for our generic products (including from other pharmaceutical companies and as a result of increased governmental pricing pressures), competition for our specialty pharmaceutical businesses, our ability to achieve expected results through our specialty, including innovative, R&D efforts, the effectiveness of our patents and other protections for innovative products, decreasing opportunities to obtain U.S. market exclusivity for significant new generic products, our ability to identify, consummate and successfully integrate acquisitions and license products, our ability to reduce operating expenses to the extent and during the timeframe intended by our cost restructuring program, uncertainties relating to the replacement of and transition to a new President & Chief Executive Officer, the effects of increased leverage as a result of recent acquisitions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our potential exposure to product liability claims to the extent not covered by insurance, increased government scrutiny in both the U.S. and Europe of our settlement agreements with brand companies and liabilities arising from class action litigation and other third-party claims relating to such agreements, potential liability for sales of generic medicines prior to a final resolution of outstanding patent litigation, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, any failures to comply with complex

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974



Press Release

for
immediate
release

Medicare and Medicaid reporting and payment obligations, governmental investigations into sales and marketing practices, particularly for our specialty medicines (and our ongoing FCPA investigations and related matters), uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology-based medicines, adverse effects of political or economic instability, corruption, major hostilities or acts of terrorism on our significant worldwide operations, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, any failure to retain key personnel or to attract additional executive and managerial talent, the impact of continuing consolidation of our distributors and customers, variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, the termination or expiration of governmental programs or tax benefits, environmental risks, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2012 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 the Company undertakes no obligation to update or revise any forward looking statement, whether as a result of new information, future events or otherwise.

###

IR Contacts:	Kevin C. Mannix	United States	(215) 591-8912
	Ran Meir	United States	(215) 591-3033
	Tomer Amitai	Israel	972 (3) 926-7656
PR Contacts:	Iris Beck Codner	Israel	972 (3) 926-7687
	Denise Bradley	United States	(215) 591-8974