TEVA ANNOUNCES UPDATES TO ONCOLOGY BIOLOGIC PORTFOLIO

- First EU launch for LONQUEX® (long-acting G-CSF) in Germany; Teva launches GRANIX™ (short-acting G-CSF) launched in the US
- Balugrastim Biologics License Application (BLA) withdrawn from FDA review process pending provision of additional confirmatory data

Jerusalem, November 18, 2013 – Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) today announced two significant additions to its global oncology biologic portfolio with the recent launches of LONQUEX® (lipegfilgrastim) and GRANIX™ (tbo-filgrastim) Injection, and an update on the review status of balugrastim by the U.S. Food and Drug Administration (FDA).

Teva launched LONQUEX® (long-acting G-CSF) in Germany on November 4, 2013 – the first launch as part of an EU-wide approval. Teva plans to continue the roll-out of Lonquex across additional countries covered by the European Marketing Approval over the coming months. Also this month, Teva launched GRANIX™ (short-acting G-CSF) in the U.S. on November 11, 2013, marking the entry of the first new G-CSF to the US market in more than ten years. LONQUEX® and GRANIX™ provide new treatment options for physicians who are seeking to reduce the duration of severe neutropenia in patients with non-myeloid malignancies, who are receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

“Managing the duration of severe neutropenia is critical to optimal cancer care, because it can disrupt the delivery of cancer treatments,” said Lee S. Schwartzberg, M.D., Division Chief, Hematology & Oncology, at the University of Tennessee Health Science Center. “With the availability of more G-CSF treatment options, healthcare professionals and their patients with non-myeloid malignancies undergoing myelosuppressive chemotherapy will be able to choose the G-CSF that best suits their needs.”

“Teva is committed to commercializing G-CSFs globally and is continuing to build the portfolio of short- and long-acting G-CSFs in this important, patient-focused category of medicines,” said Rob Koremans, M.D., President and CEO of Teva Global Specialty Medicines. “By making these treatment options available to physicians and their patients, our goal is to make a meaningful difference in the lives of those with cancer.”

Last week, the company withdrew its balugrastim Biologics License Application (BLA) from the FDA review process following ongoing consultation with the agency in preparation for the late cycle review meeting, pending the provision of additional confirmatory data. The FDA has agreed to work with Teva in designing any additional studies that may be required in support of the BLA for balugrastim. The company is currently assessing its options with regard to its long-acting G-CSF program in order to define an approach that will best serve patient needs going forward.
About Neutropenia
Neutropenia is a hematological disorder characterized by an abnormally low number of neutrophils. A person with severe neutropenia has an absolute neutrophil count that is less than 500 mm$^2$ and has a high risk of infection. Neutrophils usually make up 40-60 percent of circulating white blood cells and serve as the primary defense against infections by destroying bacteria in the blood. When chemotherapy agents attack cancer cells in the body, neutrophils and other cells are also attacked. This results in a decrease in healthy white blood cells, making it harder for the body to fight infections. Patients receiving chemotherapy are at risk of becoming neutropenic and can become susceptible to infections that may become life-threatening.

About G-CSF
G-CSF is a naturally occurring hormone that is produced by the body to stimulate the bone marrow to produce neutrophils, a type of white blood cell that helps the immune system fight infection. A recombinant form of G-CSF is used to treat certain cancer patients with neutropenia in order to stimulate the bone marrow to produce more white blood cells.

About Granix™
GRANIX™ is a leukocyte growth factor indicated for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

The safety of GRANIX™ was evaluated in three Phase 3 clinical trials in patients receiving myelosuppressive chemotherapy for breast cancer, lung cancer, and non-Hodgkin lymphoma (NHL). In a Phase 3 clinical study, GRANIX™ demonstrated a 71 percent reduction in the duration of severe neutropenia when compared to placebo. GRANIX™ significantly reduced the duration of severe neutropenia when compared to placebo (1.1 days vs. 3.8 days). The efficacy of GRANIX was evaluated in a multinational, multicenter, randomized, controlled Phase 3 study of chemotherapy-naïve patients with high-risk stage II, stage III, or stage IV breast cancer receiving a myelosuppressive regimen of doxorubicin (60 mg/m$^2$ IV bolus) and docetaxel (75 mg/m$^2$). Comparisons with placebo occurred in the first cycle.

Important Safety Information
- **Splenic rupture:** Splenic rupture, including fatal cases, can occur following the administration of human granulocyte colony-stimulating factors (hG-CSFs). Discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture in patients who report upper abdominal or shoulder pain after receiving GRANIX.

- **Acute respiratory distress syndrome (ARDS):** ARDS can occur in patients receiving hG-CSFs. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.

- **Allergic reactions:** Serious allergic reactions, including anaphylaxis, can occur in patients receiving hG-CSFs. Reactions can occur on initial exposure. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.
• **Use in patients with sickle cell disease:** Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving hG-CSFs. Consider the potential risks and benefits prior to the administration of GRANIX in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.

• **Potential for tumor growth stimulatory effects on malignant cells:** The granulocyte colony-stimulating factor (G-CSF) receptor, through which GRANIX acts, has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded. 4

• **Most common treatment-emergent adverse reaction:** The most common treatment-emergent adverse reaction that occurred in patients treated with GRANIX at the recommended dose with an incidence of at least 1% or greater and two times more frequent than in the placebo group was bone pain.

You are encouraged to report side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please click [here](http://www.fda.gov/medwatch) to view the Full Prescribing Information for GRANIX.

To view multimedia content for GRANIX™, please click: [www.TheGranixchoice.com](http://www.TheGranixchoice.com)

**About Lonquex® (lipegfilgrastim)**

Lonquex® is a new long-acting recombinant granulocyte colony-stimulating factor (G-CSF) treatment granted approval by the European Medicines Agency indicated for reduction in the duration and incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes).

Human G-CSF (filgrastim) is a polypeptide that regulates the production and release of functional neutrophils from the bone marrow. Lonquex® is a glycoPEGylated, long-acting form of recombinant human filgrastim, classified with a unique Anatomical Therapeutic Chemical (ATC) Classification System code, with a sustained duration of action due to decreased renal clearance. The efficacy and tolerability of Lonquex® has been assessed in a full clinical development program. Phase I PK and PD studies in healthy volunteers demonstrate a marked increase in blood neutrophil counts within 24 hours of administration, as well as an increase in the antibacterial activities of neutrophils.

In a pivotal Phase III active-controlled study in 202 patients with stage II-IV breast cancer receiving up to four cycles of chemotherapy consisting of doxorubicin and docetaxel, patients were randomized 1:1 to receive 6 mg Lonquex® or 6 mg pegfilgrastim. The study met the primary efficacy endpoint, DSN in the first cycle of chemotherapy, demonstrating non-inferiority of 6 mg Lonquex® to 6 mg pegfilgrastim (p=0.126), with a comparable tolerability profile. (DSN was calculated as the sum of all days after CTX with ANC <0.5 x 10⁹/L.) Secondary endpoints were favorable for Lonquex®, including an overall mean faster time of 1.5 days to Absolute Neutrophil Count (ANC) recovery of in cycle 1, a trend that was maintained up to cycle 3 (ATP population). (ANC recovery defined as a return of ANC to ≥ 2.0x10⁹/L.)

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A second Phase III study in 375 patients at low risk of febrile neutropenia (FN 10-20%) with non-small cell lung cancer was undertaken, comparing 6 mg Lonquex® (n=250) with placebo (n=125). The primary endpoint, incidence of FN in the first cycle of chemotherapy, did not reach statistical significance (p=0.1151). FN is defined as an ANC count of <0.5×10^9/L with fever (oral body temperature >38.5°C on ≥2 consecutive measurements ≥60 minutes apart.) Secondary endpoint analyses showed a positive trend in favor of Lonquex® vs placebo: duration and incidence of severe neutropenia in cycle 1 was consistently shorter (mean 2.3 ± 2.5 days; p<0.0001) and lower (32.1% vs 59.2%; p<0.0001) in the lipegfilgrastim group overall (mean 0.6 ± 1.1 days) compared with the placebo group. (SN defined as grade 4 neutropenia with an ANC <0.5 x 10^9/L.) Although incidence of death at study end was 7.2 % (placebo) and 12.5 % (6 mg lipegfilgrastim), the overall incidence of death at the 360-day follow-up was similar between placebo and lipegfilgrastim (44.8 % and 44.0 %, respectively; safety population).

The tolerability of lipegfilgrastim has been evaluated based on results from clinical studies including 506 patients and 76 healthy volunteers treated at least once with lipegfilgrastim. The most common adverse reactions (≥ 1/100 to < 1/10) included: thrombocytopenia, hypokaleamia, headache, erythema and chest pain, with musculoskeletal pains listed as very common (≥ 1/10).

One 6 mg dose of Lonquex® (a single pre-filled syringe) is recommended for adults for each chemotherapy cycle, given approximately 24 hours after cytotoxic chemotherapy.

Lonquex® treatment should be initiated and supervised by physicians experienced in oncology or haematology. Please consult the SmPC for further information, including regarding adverse events, special warnings and precautions for use.

This medicinal product is subject to additional monitoring which will allow Teva to quickly identify new safety information. Healthcare professionals are encouraged to report any suspected adverse reactions to PatientSafety@tevapharm.com

**About Balugrastim**

Balugrastim is a once per cycle leukocyte growth factor. The proposed indication is to decrease the duration of severe neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

**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.
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 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.

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Teva Pharmaceuticals
(Teva Pharmaceuticals USA, Inc. NYSE: TEVA)

Teva announced today two important updates to its biologic product portfolio—global oncology with the launch of Lonquex® (lipegfilgrastim) and GRANIX™ (tbo-filgrastim)—as well as an update on the regulatory process of Balugrastim by the FDA in preparation for the submission of a Biologics License Application (BLA) for this product.

Lonquex®, a long-acting G-CSF, was launched in Germany in November 2013, becoming the first country in Europe to approve the product for all of the European Union. Teva plans to extend the launch of Lonquex® to additional countries covered under the European Medicines Agency’s (EMA) marketing authorization in the coming months.

Also in November, GRANIX™ was launched in the United States, making it the first G-CSF product to enter the American market in over a decade.

Lonquex® and GRANIX™ provide additional treatment options for physicians who seek to minimize the incidence of severe neutropenia (a sudden decrease in white blood cell count) that can result from chemotherapy for cancer.

“Managing severe neutropenia is critical for optimal cancer treatment because this can make a real difference in how we treat patients,” said Dr. Lee S. Schwartzberg, Medical Director and Oncologist at the University of Tennessee Medical Center.

When more treatment options exist—both for physicians and patients suffering from cancer—choosing the most appropriate can make a significant impact on the quality of patients’ lives.

In the past week, the company formally submitted a request for a biologic license application (BLA) to the FDA for Balugrastim, in coordination with a meeting with the agency, subject to additional data to be submitted. The FDA agreed to work with Teva to design future clinical trials that the company will submit in the framework of the BLA for Balugrastim.

Neutropenia

Neutropenia is defined as a condition in which a patient has a white blood cell count below 233 per cu mm. Patients suffering from severe neutropenia have a white blood cell count of less than 233 per cu mm. They are at high risk for infections. Neutrophils constitute 43±23% of white blood cells and serve as the first line of defense against infections.

G-CSF is a natural hormone in the body that stimulates the production of neutrophils in the bone marrow. Neutrophils are a type of white blood cell used as the first line of defense against infections.
**Important Safety Information**

- **Splenic rupture:** Splenic rupture, including fatal cases, can occur following the administration of human granulocyte colony-stimulating factors (hG-CSFs). Discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture in patients who report upper abdominal or shoulder pain after receiving GRANIX.

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- **Most common treatment-emergent adverse reaction:** The most common treatment-emergent adverse reaction that occurred in patients treated with GRANIX at the recommended dose with an incidence of at least 1% or greater and two times more frequent than in the placebo group was bone pain.

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Please click here to view the Full Prescribing Information for GRANIX.

To view multimedia content for GRANIX™, please click: www.TheGranixchoice.com
long-acting (lipegfilgrastim) Lonquex® (recombinant granulocyte colony stimulating factor) is a new and improved formulation of the commonly used G-CSF, which stimulates white blood cell production. Lonquex® is a long-acting pegfilgrastim formulation, dosed once every 28 days, to reduce the frequency of hematopoietic growth factor injections in patients receiving chemotherapy.

In a phase II/III study, Lonquex® was compared to placebo in patients receiving pegfilgrastim. The primary endpoint was the duration of febrile neutropenia (≥[38°C]). Patients received Lonquex® or placebo as a single dose before chemotherapy. At the end of chemotherapy, the duration of febrile neutropenia was 21.2 ± 10.0 days for the Lonquex® group versus 6.2 ± 1.1 days for the placebo group (p<0.0001).

Secondary endpoints included:
- Duration of hospitalization:
  - 92 days for the Lonquex® group versus 23 days for the placebo group (p<0.0001).
- Duration of fever:
  - 0.9 ± 0.5 days for the Lonquex® group versus 6.0 ± 1.0 days for the placebo group (p<0.0001).
- Duration of ANC nadir:
  - 9.0 ± 3.0 days for the Lonquex® group versus 23 days for the placebo group (p<0.0001).
- Hospital readmissions:
  - 0.6 ± 0.9 for the Lonquex® group versus 0.7 ± 1.0 for the placebo group (p=0.1511).

Lonquex® demonstrated a clinically meaningful improvement in all endpoints compared to placebo, with a statistically significant and clinically relevant reduction in febrile neutropenia in patients receiving chemotherapy. Lonquex® is recommended for use in patients receiving chemotherapy, particularly in high-risk populations such as those with bone marrow suppression.

PatientSafety@tevapharm.com
biopharmaceutical products, competition for our innovative products, 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, 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 agreements with brand companies, potential liability for sales of generic products 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 Medicare and Medicaid reporting and payment obligations, governmental investigations into sales and marketing practices (particularly for our specialty pharmaceutical products), uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products, adverse effects of political or economical 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, 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.

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