Teva Receives European Marketing Authorization for Lonquex® (XM22 lipegfilgrastim)

JERUSALEM, Aug 08, 2013 -- Teva Pharmaceutical Industries Ltd (NYSE: TEVA) announced today that the European Commission has granted marketing authorization for Lonquex® (lipegfilgrastim). This approval provides the regulatory framework for the commercialization of Lonquex® in all twenty eight countries of the European Union plus Norway, Iceland and Liechtenstein.

Lonquex® is a long-acting recombinant granulocyte colony-stimulating factor (G-CSF) with the active ingredient lipegfilgrastim – a novel glycoPEGylated (PEG; polyethylene glycol) filgrastim molecule. Lonquex® (lipegfilgrastim) is indicated for the reduction of the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes). Lonquex® is intended as a once-per-cycle fixed dose, subcutaneous injection for neutrophil support in cancer patients receiving myelosuppressive chemotherapy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes).1

“This is an important milestone for Teva Specialty Medicines in Europe and demonstrates our commitment to making a difference to the lives of those with cancer” said Dr. Rob Koremans, President and CEO of Teva Specialty Medicines. “Lonquex® is an alternative G-CSF treatment for helping manage neutropenia during myelosuppressive chemotherapy. The European approval comes earlier than expected, just 8 weeks after the positive CHMP opinion. We look forward to providing this oncology supportive care treatment option in all European Union member states.”

Lonquex® has undergone a full clinical development program, including pre-clinical to clinical in vivo studies, as part of the efficacy and tolerability assessment for use with chemotherapy patients.

Dr. Michael Hayden, Teva’s President of Global R&D and Chief Scientific Officer, commented: “Effective prevention and treatment of febrile neutropenia is an important consideration for clinicians managing cancer patients who are undergoing cytotoxic chemotherapy. As well as targeting cancer cells, chemotherapy affects rapidly-dividing bone marrow cells, thereby dramatically reducing a patient's ability to fight off infection, with potentially serious consequences. This approval is testament to Teva’s commitment to bringing new and alternative treatments to market to support clinicians in caring for patients.”

About Chemotherapy-Induced Neutropenia (CIN)
Chemotherapy-induced neutropenia (CIN), is a common and potentially life-threatening side-effect of chemotherapy treatment characterized by a decreased level of white blood cells (known as neutrophils). CIN can result in bacterial infections, which can compromise patients’ health. The EORTC Guidelines recommend prophylactic G-CSF treatment for chemotherapy patients with an overall high risk (≥20%) of developing febrile neutropenia (FN) to help avoid the risks associated with a low neutrophil count. The side effects of CIN can result in the requirement for chemotherapy dose modifications. Disruption to the treatment schedule can reduce the anti-cancer effects of chemotherapy, which may subsequently affect treatment outcomes.

* Febrile neutropenia is defined as an absolute neutrophil count (ANC) of <0.5 × 10⁹/L, or <1.0 × 10⁹/L predicted to fall below 0.5 × 10⁹/L within 48 h, with fever or clinical signs of sepsis

Product Information about Lonquex®

The marketing authorization of Lonquex® (lipegfilgrastim) brings an additional long-acting G-CSF treatment choice to clinicians managing the effects of CIN in patients with cancer in Europe (alongside other currently marketed G-CSFs: short-acting filgrastim and long-acting pegfilgrastim).

Human G-CSF (filgrastim) is a glycoprotein that regulates the production and release of functional neutrophils from the bone marrow. Lonquex® (lipegfilgrastim) is a glycoPEGylated, long-acting form of recombinant human filgrastim, classified with a distinct ATC code, with a sustained duration of action due to decreased renal clearance. Pharmacokinetic effects demonstrate a marked increase in blood neutrophil counts within 24 hours of administration, while increasing the antibacterial activities of neutrophils. The efficacy and tolerability of Lonquex® has been assessed in a pivotal Phase III multinational, multicentre, randomised, double-blind, controlled non-inferiority study. Results demonstrated non-inferiority of Lonquex® to pegfilgrastim (6mg equivalent doses) in chemotherapy-naïve high risk stage II, III or IV breast cancer patients (n=202) receiving doxorubicin/docetaxel chemotherapy, regarding duration of severe neutropenia (DSN) in the first cycle (p=0.126). Secondary efficacy endpoints showed comparable results for Lonquex® and pegfilgrastim regarding duration of severe neutropenia (0.9 ± 0.9 vs 0.7 ± 1.0 with Lonquex®), incidence of severe neutropenia (51.5% vs 43.6% with Lonquex®) and incidence of febrile neutropenia (3% vs 1% with Lonquex®) in Cycle 1.

A second phase III multinational, multicenter, randomised, double-blind placebo-controlled study was undertaken comparing 6mg Lonquex® (n=250) with placebo (n=125) in low risk (FN 10-20%), non-small cell lung cancer patients (NSCLC). The primary endpoint, incidence of FN (defined as an ANC count of <0.5×10⁹/L with fever [oral body temperature >38.5°C on ≥2 consecutive measurements ≥60 minutes apart]) in the first cycle of chemotherapy did not reach statistical significance (p=0.1151). Secondary endpoint analyses showed a positive trend in favour of Lonquex® vs placebo: duration of severe neutropenia (i.e. ANC value <0.5×10⁹/L) in cycle 1 was consistently shorter in the lipegfilgrastim group overall (mean 0.6 ± 1.1 days).
compared with the placebo group (mean 2.3 ± 2.5 days; p<0.0001). Incidence of severe neutropenia was much lower in the lipegfilgrastim group compared with the placebo group (32.1% vs 59.2%; p<0.0001) in Cycle 1.¹

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) include: thrombocytopenia, hypokaleamia, headache, erythema and chest pain, with musculoskeletal pains listed as very common (≥ 1/10).¹

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.¹

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.¹

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

*ATC: Anatomical Therapeutic Chemical (ATC) Classification System
**ANC recovery defined as a return of ANC to > 2,0x10⁹/L

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.


Lonquex® is a registered trademark of Teva Pharmaceutical Industries Ltd. Teva holds exclusive marketing rights for Lonquex® in all European countries.
1. Lonquex® (lipegfilgrastim) Summary of Product Characteristics (Aug 2013)


SOURCE: Teva Pharmaceutical Industries Ltd.
REF: HQ/LNQX/13/0006

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 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, including our ability to develop, manufacture, market and sell 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 product 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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<table>
<thead>
<tr>
<th>IR Contacts:</th>
<th>Kevin C. Mannix</th>
<th>United States</th>
<th>(215) 591-8912</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ran Meir</td>
<td>United States</td>
<td>(215) 591-3033</td>
</tr>
<tr>
<td></td>
<td>Tomer Amitai</td>
<td>Israel</td>
<td>972 (3) 926-7656</td>
</tr>
<tr>
<td>PR Contacts:</td>
<td>Iris Beck Codner</td>
<td>Israel</td>
<td>972 (3) 926-7687</td>
</tr>
<tr>
<td></td>
<td>Denise Bradley</td>
<td>United States</td>
<td>(215) 591-8974</td>
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Natural killer cells can be activated by G-CSF, the long-acting recombinant form of growth factor CSF-1 (colony stimulating factor-1). G-CSF is used to stimulate the production of neutrophils in patients undergoing chemotherapy, especially in cases of high-risk chemotherapy protocols. The European Medicines Agency approved Lonquex® (lifegfilgrastim) for the treatment of neutropenic fever in patients over the age of 65 years old who are undergoing chemotherapy. Lonquex® is intended to be administered subcutaneously once every two weeks to support neutrophils in patients receiving chemotherapy, except for acute myeloid leukemia and myelodysplastic syndromes.

Information about Lonquex® The approval of Lonquex® (lifegfilgrastim) for the treatment of neutropenic fever in patients over the age of 65 years old who are undergoing chemotherapy is a significant milestone for Teva’s unique portfolio in Europe, highlighting our commitment to improving the lives of those suffering from cancer.” Dr. Avi Korzner, President and CEO of Teva’s Specialized Medicine Division.

“Lonquex® is an alternative treatment that helps patients cope with the effects of neutropenia during chemotherapy. The European approval came earlier than expected, eight weeks after the positive opinion of the European Committee for Medicinal Products for Human Use. We are looking forward to providing this innovative and alternative treatment in all EU countries.”

Information about neutropenia Neutropenia is a side effect of chemotherapy that can lead to serious infections. Clinical guidelines of the European Union recommend the use of growth factors such as CSF-1 (granulocyte colony-stimulating factor) for high-risk patients with neutropenic fever to prevent serious infections. However, the treatment of neutropenia is often delayed or untreated due to the scarcity of effective and affordable solutions.

About Teva Teva (NYSE:TEVA) is the leading global pharmaceutical company with a portfolio of medicines and medical devices that address unmet needs for patients around the world.

iris.beckcodner@teva.co.il 03-9267683 tomter.amitai@teva.co.il 03-9267656
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Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

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