

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
November 07, 2007

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
under the Securities Exchange Act of 1934**

For the month of November 2007

Commission File Number 0-16174



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**Teva Pharmaceutical Industries Limited**

(Translation of registrant's name into English)

**5 Basel Street, P.O. Box 3190**

**Petach Tikva 49131 Israel**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82- \_\_\_\_\_

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Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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Marjie Hadad	Gamida Cell Ltd.	972-54-536-5220
Dan Suesskind, Chief Financial Officer George Barrett,	Teva Pharmaceutical Industries Ltd.	972-2-941-1717
Corp. E. V.P. - Global pharmaceutical Markets Chief Executive Officer	Teva Pharmaceutical Industries Ltd. Teva North America	(215) 591-3030
Liraz Kalif /	Teva Pharmaceutical Industries Ltd. Teva North America	972-3-926-7281 (215) 591-8912
Kevin Mannix, Investor Relations		

For Immediate Release

**First Patient Undergoes Expanded Cord Blood Transplant in the ExCell Registration Study of StemEx<sup>&reg</sup> for Leukemia and Lymphoma**

*Patients are now being enrolled in the U.S. for the Gamida Cell-Teva Joint Venture ExCell trial studying StemEx<sup>&reg</sup> as an alternative treatment for bone marrow transplants.*

**Jerusalem, Israel, (November 6, 2007)** --- The Gamida Cell-Teva Joint Venture announced today that the first patient in the international, pivotal registration ExCell study has undergone a StemEx<sup>&reg</sup> transplant at the Ireland Cancer Center of University Hospitals Case Medical Center. StemEx<sup>&reg</sup> is a graft of expanded stem/progenitor cells,

derived from a single unit of umbilical cord blood and transplanted in combination with non expanded cells from the same unit.

The single arm, multi-center ExCell study will assess the efficacy and safety of the StemEx<sup>&reg</sup> transplantation as a treatment for hematological malignancies, including leukemia and lymphoma. The U.S. Food and Drug Administration (FDA) granted ExCell a Special Protocol Assessment (SPA) in October 2006 and StemEx<sup>&reg</sup> orphan drug status in March 2005.

"We are pleased to report that we have conducted the first StemEx<sup>&reg</sup> transplant in the ExCell study," said Mary J. Laughlin, MD, Associate Professor of Medicine and a Dr. Donald and Ruth Weber Goodman Professor of Innovative Cancer Therapeutics at Case Western Reserve University, a hematologist/oncologist at the Ireland Cancer Center of University Hospitals Case Medical Center, and one of the study's principal investigators. "There is a need for improved options for patients, who cannot find a matched bone marrow donor, that will expedite the matching process and decrease rates of transplant related mortality and Graft versus Host Disease (GvHD)."

According to the National Marrow Donor Program, each year in the United States alone, more than seventy percent of the 35,000 patients with life-threatening diseases who could benefit from a marrow transplant cannot be matched with a donor. Cord blood has less matching requirements than bone marrow or peripheral blood transplants, providing the potential to increase the number of suitable transplant matches and to shorten the time it can take to find a match. However, there are a limited number of stem/progenitor cells in cord blood, enabling a quantity sufficient generally only for pediatric treatment. StemEx<sup>&reg</sup> employs a technology that expands this small number of cord blood stem/progenitor cells, increasing their therapeutic capacity for transplantation in adolescents and adults.

"Cell therapy products are no longer a vision of the future, but a solid deliverable for the present," said Gamida Cell CEO Dr. Yael Margolin. "We are excited to advance the clinical development of StemEx<sup>&reg</sup> and will continue with our efforts to bring this first of a kind product to market."

StemEx<sup>&reg</sup> is being developed by a Joint Venture equally owned and managed by Gamida Cell and Teva Pharmaceutical Industries (NASDAQ: TEVA).

"StemEx<sup>&reg</sup> is an important innovation and an exciting part of Teva's research and development pipeline," said Dr. Aharon Schwartz, Vice President, Innovative Ventures from Teva. "We are committed to working with Gamida Cell and look forward to the potential of providing an improved treatment option for patients with hematological cancers."

## **About the Study**

The full title of the ExCell study is *A Multi-Center, Multi-National, Historical Cohort Controlled Study to Evaluate Efficacy and Safety of Transplantation of StemEx<sup>®</sup>, Umbilical Cord Blood Stem and Progenitor Cells Expanded Ex Vivo, in Subjects with Hematologic Malignancies Following Myeloablative Therapy.*

The Phase I/II study, conducted at The University of Texas M. D. Anderson Cancer Center in Houston, showed preliminarily positive results, which prompted the registration ExCell study and its further investigation of the safety and efficacy of StemEx<sup>®</sup>.

The ExCell study is currently enrolling 100 patients, ages 12 to 55, with high-risk hematological malignancies, who do not have a matched, family-related bone marrow donor, and who meet all of the eligibility criteria of the study. The study will take place in 11 of the leading cord blood transplantation centers in the United States, Europe and Israel. Additional information regarding study parameters and participating sites may be accessed at (<http://clinicaltrials.gov/ct/show/NCT00469729>).

#### **About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

[www.tevapharm.com](http://www.tevapharm.com)

#### **About Gamida Cell**

Gamida Cell is developing a line of cell therapy products for the treatment of debilitating and fatal diseases with unmet clinical needs such as cancer, cardiovascular disease and neurological disorders. The company is dedicated to making a significant difference in the clinical practice of modern medicine by first producing, then tapping into the regeneration power of an ample body of therapeutic stem/progenitor cells. Gamida Cell's technologies are simple, reversible, do not involve genetic interference, and are easily scalable. Current shareholders include Elbit Imaging, Biomedical Investments, IHCV, Teva Pharmaceutical Industries (NASDAQ: TEVA), Denali Ventures, and Auriga Ventures. For additional information please visit: [www.gamida-cell.com](http://www.gamida-cell.com).

#### **About University Hospitals**



With 150 locations throughout Northeast Ohio, University Hospitals serves the needs of patients through an integrated network of hospitals, outpatient centers and primary care physicians. At the core of our Health System is University Hospitals Case Medical Center. The primary affiliate of Case Western Reserve University School of Medicine, University Hospitals Case Medical Center is home to some of the most prestigious clinical and research centers of excellence in the nation and the world, including cancer, pediatrics, women's health, orthopedics and spine, radiology and radiation oncology, neurosurgery and neuroscience, cardiology and cardiovascular surgery, organ transplantation and human genetics. Its main campus includes the internationally celebrated Rainbow Babies & Children's Hospital, ranked best in the Midwest and first in the nation for the care of critically ill newborns; MacDonald Women's Hospital, Ohio's only hospital for women; and Ireland Cancer Center, which holds the nation's highest designation by the National Cancer Institute of Comprehensive Cancer Center. For more information, go to [www.uhhospitals.org](http://www.uhhospitals.org)

*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 Teva's 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: Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which Teva may obtain U.S. market exclusivity for certain of its new generic products and regulatory changes that may prevent Teva from utilizing exclusivity periods, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Allegra<sup>®</sup>, Neurontin<sup>®</sup>, Lotrel<sup>®</sup>, and Famvir<sup>®</sup>, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> sales, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to achieve expected results through our innovative R&D efforts, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, and other factors that are discussed in Teva's Annual Report on Form 20-F and its 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.*

Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Dan Suesskind

Name: Dan Suesskind  
Title: Chief Financial Officer

Date : November 6 , 2007

