

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
February 17, 2005

**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 February 2005

Commission File Number 0-16174



*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   X  

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   X  

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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**FOR IMMEDIATE RELEASE**

## **Teva and Gamida-Cell Will Develop and Commercialize StemEx<sup>®</sup> for the Treatment of Leukemia**

### **Preparations Underway to Commence Phase II/III Study**

**Jerusalem, Israel, February 16, 2005** - Teva Pharmaceutical Industries Ltd. and Gamida-Cell Ltd. announced today that Teva exercised the option to enter into a joint venture with Gamida-Cell Ltd. to develop and commercialize StemEx<sup>®</sup> for the treatment of Leukemia and Lymphoma. As part of the investment in Gamida-Cell in 2003, Teva held an option to jointly complete the development and globally commercialize StemEx<sup>®</sup>. Teva will invest under certain conditions up to \$25 million in the joint venture.

Currently, only 15% of patients requiring bone marrow transplantation, who do not have genetically matched relatives, are able to find matching donors. StemEx<sup>®</sup> developed by Gamida-Cell, based on inventions made in the Hadassah hospital in Jerusalem, is cord blood highly enriched with stem cells. StemEx<sup>®</sup> has the potential to fulfill a life saving unmet need for the majority of the patients who cannot find matching donors. This was shown by data from the recent Gamida-Cell Phase I/II study presented at the annual conference of the American Society for Hematology (December 2004).

Mr. Israel Makov, President and CEO of Teva Pharmaceutical Industries said, "The investment and exercise of the option with Gamida-Cell are part of Teva's strategy to enter into the field of Cell-Therapy. As part of this strategy Teva led the Israeli cell therapy consortium "Genesis", and in addition to Gamida-Cell, invested in Proneuron, an Israeli company developing cell-based therapies for complete spinal cord injury. Teva believes in the potential of Cell Therapy and is committed to bringing to the world market new therapies based on Israeli science."

Teva and Gamida plan to meet the Food and Drug Administration and other regulatory agencies in order to finalize the parameters for the pivotal study. The companies hope to initiate this study in the second half of 2005.

"Gamida-Cell is pleased to continue and expand the collaboration with TEVA. It is our intention to begin the pivotal Phase II/III study of StemEx<sup>®</sup> and secure fast track designation," said Gamida-Cell CEO Mr. Ehud Marom. "The execution of our agreement with Teva places Gamida-Cell in the lead of the emerging, multi billion dollar Cell Therapy market."

**Teva Pharmaceutical Industries Ltd.**, headquartered in Israel, is among the top 25 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva's sales are in North America and Europe.

**Gamida-Cell Ltd.** ([www.gamida-cell.com](http://www.gamida-cell.com)) is a leader in the expansion of hematopoietic (blood) stem cell therapeutics in clinical development for cancer and autoimmune diseases, as well as future regenerative cell-based medicines including cardiac and pancreatic repair. Major shareholders are Elscint (Europe-Israel), Biomedical Investments, Denali Ventures, Teva, Auriga Ventures, Pamot and Comsor.

*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 Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell or license their own generic products (so called "authorized generics") or successfully extend the exclusivity period of their branded products, the effects of competition on Copaxone's sales, including potential competition from the launch of Tysabri, Teva's ability to rapidly integrate the operations of acquired businesses, including its acquisition of Sicor Inc., regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to completion of appellate litigation, including that relating to Neurontin, 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 Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva's ability to successfully identify, consummate and integrate acquisitions, exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations outside the United States that may be adversely affected by terrorism or major hostilities, fluctuations in currency, exchange and interest rates, operating results 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 publicly or revise any forward-looking statement, whether as a result of new information, future developments 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: February 16, 2005



