



## **XYOTAX™ Receives Fast Track Designation for the Treatment of Advanced Non-Small Cell Lung Cancer from FDA**

Fast track designation granted on basis of preliminary anti-cancer activity

**June 16, 2003 Seattle**—Cell Therapeutics, Inc. (CTI) (NASDAQ: CTIC) received fast track designation from the U.S. Food and Drug Administration (FDA) for XYOTAX™ (CT-2103), its polyglutamate paclitaxel, for the treatment of advanced non-small cell lung cancer (NSCLC) in patients with a poor performance status (PS2). Fast track designation was granted because NSCLC in PS2 patients is incurable with available therapy offering only modest benefit, and XYOTAX™ has the potential to demonstrate improvement over available therapy in these patients based on anticancer activity (tumor shrinkage) in phase I and II clinical trials.

“We are extremely pleased that the FDA recognizes that this population of patients has few viable treatment alternatives and that XYOTAX™ has the potential to offer improvement over existing therapies,” stated James A. Bianco, M.D., President and CEO of CTI. “Fast track designation of XYOTAX™ represents a major regulatory milestone in the development of this product candidate.”

XYOTAX™ is currently in two phase III clinical trials for PS2 patients with advanced NSCLC. A new drug application for this indication is targeted for the end of 2004. XYOTAX™ is also being studied in a phase III clinical trial among patients with non-small cell lung cancer who have relapsed following a single platinum-containing front-line treatment.

According to the American Cancer Society ([www.cancer.org](http://www.cancer.org)), approximately 172,000 new cases of lung cancer are expected during 2003. Non-small cell lung cancer accounts for almost 80 percent of lung cancer cases and PS2 patients make up roughly 20 to 30 percent of the newly diagnosed advanced NSCLC patients.

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## Fast Track Designation

Fast track designation means the FDA will facilitate and expedite the development and review of the application for the approval of a new drug if it is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address an unmet medical need. An expedited review as defined by the FDA user fee performance goals provides for a review within six months.

## About XYOTAX™

XYOTAX™ (pronounced Zi-ō-tāks) is a pharmaceutical that links paclitaxel, the active ingredient in Taxol®, to a biodegradable polyglutamate polymer. This polymer technology results in a new chemical entity, designed to selectively deliver higher and potentially more effective levels of active chemotherapeutics to tumors. Blood vessels in tumor tissue, unlike blood vessels in normal tissue, are porous to molecules like polyglutamate. Based on preclinical studies, it appears that XYOTAX™ is preferentially trapped in the tumor blood vessels allowing significantly more of the dose of chemotherapy to localize in the tumor. Because more of the chemotherapy is targeted to the tumor and the levels of chemotherapy delivered to normal tissue are reduced, XYOTAX™ may be potentially more effective and have less severe side effects than currently available chemotherapeutics.

## About Cell Therapeutics, Inc.

Based in Seattle, CTI is a biopharmaceutical company committed to developing an integrated portfolio of oncology products aimed at making cancer more treatable. For additional information, please visit [www.cticseattle.com](http://www.cticseattle.com).

*This announcement includes forward-looking statements that involve a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results. Specifically, the risks and uncertainties that could affect the development of XYOTAX™ include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general and with XYOTAX™ in particular including, without limitation, the potential failure of XYOTAX™ to prove safe and effective for treatment of advanced non-small cell lung cancer, determinations by regulatory, patent and administrative governmental authorities, including the failure to receive approval of XYOTAX™ for treatment of advanced non-small cell lung cancer, competitive factors, technological developments, costs of developing, producing and selling XYOTAX™, and the risk factors listed or described from time to time in the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's most recent filings on Forms 10-K, 8-K, and 10-Q.*

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