

Does gender matter?

cti annual report_2005

“Medical researchers are starting to explore an intriguing prospect: that cancer behaves differently in men and women. The new insight is opening promising new avenues of research into cancer incidence and treatment.”

The Wall Street Journal, December 6, 2005



“Lung cancer causes more deaths in the United States than any other cancer. At the Lung Cancer Alliance, our initiatives aim to make fighting lung cancer a priority and change public perceptions about the disease. We applaud companies like CTI that are working to address the challenge of lung cancer treatment.”

Laurie Fenton, President, Lung Cancer Alliance



figure 1

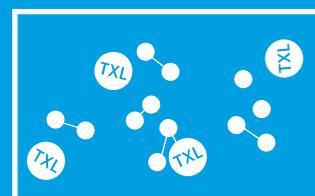


figure 2

XYOTAX is a proprietary biologically enhanced drug conjugate in which the chemotherapy agent paclitaxel is linked to a polyglutamate polymer [figure 1]. The paclitaxel-polymer conjugate allows the drug to circulate through the blood stream with minimal activity, reducing unwanted side effects in healthy tissue. Tumor blood vessels are more porous than normal blood vessels, allowing XYOTAX to pass from vessels into tumor cells, where it is trapped. Once inside the cancer cell, the biodegradable polymer is metabolized, releasing active paclitaxel [figure 2] and leading to cancer-cell death.

XYOTAX™

In 2005, we made substantial progress in advancing XYOTAX (paclitaxel poliglumex) toward the market as a treatment for non-small cell lung cancer (NSCLC). Lung cancer is the leading cause of cancer death for both men and women, and more than 80 percent of lung cancers are diagnosed as NSCLC. Despite intensive efforts to improve lung cancer outcomes, one-year and two-year survival rates for all lung cancer patients are only about 40 percent and 25 percent, respectively. For patients who have a poor performance status, survival rates are even worse.

In the first half of 2005, we presented data from more than 1,700 patients who participated in the STELLAR phase III NSCLC clinical trials. Although the three STELLAR trials did not meet their primary endpoints of superior overall survival compared with the control chemotherapies, they provided important data that will support our efforts to commercialize XYOTAX. In all three studies, XYOTAX demonstrated efficacy similar to standard therapies. There was more convenient dosing and, depending on the dose, a lower rate of severe side effects and a decreased need for supportive care.

In a pooled analysis of the STELLAR 3 and STELLAR 4 trials, there was a statistically significant improvement in survival in women treated with XYOTAX compared with controls. In addition to providing compelling data about the potential utility of XYOTAX in the treatment of NSCLC, this result raised important questions about the impact of gender on cancer therapy. Further analyses of the data have enabled us to begin answering those questions, and highlight the importance of considering biological factors in developing effective treatment strategies.

The female hormone estrogen may enhance the biodistribution and cellular metabolism of XYOTAX. As a result, women with tumors that express the estrogen receptor may receive a higher effective dose of XYOTAX compared with men, resulting in enhanced responses to the drug.

Based on these data, we initiated a confirmatory phase III trial (PIONEER) that will assess survival of chemotherapy-naive women with NSCLC who have poor performance status (ECOG PS2) when treated with XYOTAX or paclitaxel as a single agent. We are targeting the second half of 2006 for submission of a New Drug Application (NDA) for XYOTAX in the United States for women with NSCLC who are PS2, as well as a Marketing Authorisation Application (MAA) in Europe for men and women with NSCLC who are PS2.

Additionally, we advanced the development of XYOTAX as a potential treatment for ovarian cancer. In March 2005, the Gynecologic Oncology Group (GOG), a premier clinical trials cooperative, initiated a landmark pivotal phase III trial designed to evaluate the impact of monthly maintenance XYOTAX therapy on progression-free survival and overall survival in ovarian cancer patients who have achieved a complete response following standard first-line chemotherapy. The tolerability of XYOTAX may enable maintenance therapy in this indication. Previous evaluation of paclitaxel maintenance therapy required toxicity-related dose reduction. Enrollment in this 1,500-patient study is ongoing and is expected to continue throughout 2006.

“Clinical trials that exploit new data on the biology of lung cancer in women are long overdue. Outcomes will be instrumental in developing tailored therapies, possibly based on gender but even more so on the molecular biology of the disease. The exploratory data from the initial XYOTAX studies are provocative and validate the design of the PIONEER study.”

Kathy Albain, M.D., Professor of Medicine, Hematology/Oncology and Director, Thoracic Oncology and Breast Clinical Research, Loyola University Health System

“The composite analysis of STELLAR 3 and 4 provide strong support for superior efficacy of XYOTAX in women with normal estrogen levels.”

James A. Bianco, M.D., President, Chief Executive Officer, CTI

“It is important to note that XYOTAX has shown improved survival in women, but also has similar efficacy to standard agents in men, with notable safety and convenience advantages over existing therapies in both men and women, particularly when used as a single agent.”

Jack W. Singer, M.D., Chief Medical Officer, CTI

“There is some exciting emerging evidence of the role of estrogen in measuring the risk of and treating lung cancer. We are optimistic that this breakthrough science will translate into **targeted lung cancer treatments for women**, and we can give this patient group the medical attention they need.”

Joan Schiller, M.D., Melanie Heald Professor of Medical Oncology, University of Wisconsin Comprehensive Cancer Center;
President, Women Against Lung Cancer

“XYOTAX is better tolerated than many other cytotoxic agents. It is virtually never associated with alopecia or nausea. These considerations, plus the short infusion time (10 to 20 minutes), make XYOTAX an attractive chemotherapeutic agent.”

Philip D. Bonomi, M.D., Director of Medical Oncology, Rush-Presbyterian-St. Luke's Medical Center

“These data are intriguing and provide a strong scientific **link between estrogen and the effectiveness of XYOTAX**, a biologically enhanced chemotherapy agent, in treating women with lung cancer. These findings open the door to a new avenue of clinical research for gender-specific therapy.”

Mark A. Socinski, M.D., Associate Professor of Medicine, Multidisciplinary Thoracic Oncology Program,
Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

“As somebody who works as a mental health therapist, I believe this experience has helped me to connect on a very different level with my patients. I understand now what it means to be in pain or to feel despair. Having cancer is a terrifying experience, but I think it has helped me find purpose in my life.”

Cheryl Ferguson, XYOTAX clinical trial patient



Cheryl Ferguson

Both of my parents died of cancer, and I have to admit that I always suspected I would get cancer too. But it was still shocking to hear that I had lung cancer. I had always been athletic. I had a degree in physical education and worked at health clubs for a while. I had never been a big smoker, but I had a bad habit of smoking in place of eating meals, which was apparently the worst decision I ever made.

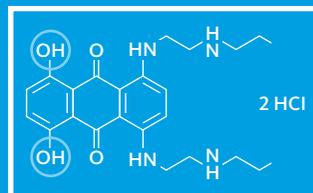
I was diagnosed with stage IIIA lung cancer on my husband's birthday in 2003. I went through all the stages of grief and loss. I hoped for the best, but I really was expecting the worst. I had radiation and chemotherapy — cisplatin and etoposide. It was a really difficult regimen, and I had to stop working. My hair fell out and I just felt sick all the time, and the infusions took several hours. After this treatment, I had surgery and had no evidence of disease. I was feeling good, getting my strength back, and even went back to work. After about a year, the cancer recurred. I asked my oncologist about experimental protocols and that's how I found out about the XYOTAX trial.

I entered the XYOTAX trial in October 2004, and it was a completely different experience from my first chemotherapy

regimen. The infusions took a lot less time, I kept my hair, and I had the energy to maintain my normal daily routine. In the spring of 2005, I developed neuropathy in my feet, and my doctor recommended that I discontinue the trial. I felt so good that I wanted to stay in, but I took his advice.

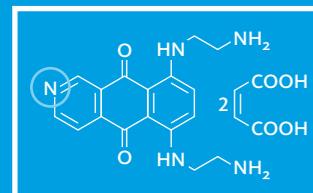
Today, I am doing well, and my disease appears to be stable. I developed brain metastases in December 2004, but they responded to radiation. Now I am volunteering as a mental health counselor and maintaining an active lifestyle. In my career, working with people who struggle to cope with life's challenges, I've realized that a positive attitude is incredibly powerful. I used that power to get through those awful months of my initial therapy, to find a clinical trial that could help, and to appreciate everything I've been given.

Having cancer gave me a totally different perspective on life. I'm not afraid anymore. I've renewed my faith, and I love stronger now than I did before I got sick. I made a list of all the things I want to do. I've taken up oil painting, and I'm even thinking about taking tap-dancing lessons. Do you know anybody who can teach a persistent, passionate 46-year-old to tap dance?



Mitoxantrone

In designing the pixantrone structure, scientists removed the OH groups in mitoxantrone that are thought to be the cause of free-radical production and cardiotoxicity.



Pixantrone

A nitrogen atom in this position in the pixantrone structure provides an improvement in pre-clinical anti-tumor activity and safety. This atom may be involved in maintaining the molecule in a planar configuration and allowing intercalation into DNA.

Pixantrone

Pixantrone is an investigational drug designed to improve the safety and activity of anthracyclines, a family of chemotherapeutic agents that are a mainstay for treating breast cancer and a variety of hematologic malignancies. Although high response rates have been observed following first-line treatment with anthracyclines, the class is associated with significant irreversible damage to the heart. As a result, there is a maximum cumulative dosage of anthracyclines beyond which continued or repeat therapy with these drugs is not recommended. Thus, patients treated with first-line anthracycline therapy may have limited options if their disease progresses or returns.

As a company committed to making cancer more treatable, we have great interest in developing an anthracycline derivative that provides similar or superior efficacy to the parent compound, while reducing or eliminating treatment-limiting toxicities. Pixantrone was identified as a promising replacement for approved anthracyclines following extensive analysis of a large number of derivative compounds. A growing body of preclinical and clinical data supports the safety and efficacy of pixantrone, and we are evaluating this investigational drug as a treatment for non-Hodgkin's lymphoma (NHL) and other cancers.

In November 2005, we presented positive data from a randomized clinical trial of pixantrone in combination with rituximab compared with rituximab alone in patients with relapsed or refractory indolent NHL. Although this study was closed in 2004 due to a change in strategy and slow enrollment, 38 patients were evaluable for safety and efficacy endpoints. The results demonstrated an 87 percent improvement in time to disease progression (TTP), the study's primary endpoint, for patients treated with pixantrone and rituximab compared with rituximab alone. The median TTP

for patients treated with combination therapy was 13.2 months, compared with 8.1 months for rituximab alone. One- and two-year progression-free survival rates were 66 percent and 44 percent for patients in the combination arm, compared with zero percent for the rituximab arm at both time points.

The study also met its secondary endpoint, demonstrating a significant improvement in objective responses, defined as a 50 percent or greater reduction in tumor size. In the combination arm, 75 percent of patients achieved a major response, with 35 percent achieving a complete response, compared with 33 percent and 11 percent, respectively, in the rituximab arm. Pixantrone was generally well tolerated, and no cases of drug-related grade 3 or 4 cardiac toxicity were reported, even though 80 percent of patients in the study had previously received anthracyclines.

We are currently conducting a pivotal phase III trial of pixantrone as a single-agent therapy in patients with relapsed aggressive NHL who have failed at least one second-line, multi-agent chemotherapy regimen. The trial is designed to assess complete response rate, TTP, and overall survival, and we expect to conduct an interim analysis of the study in the first half of 2006.

A trial evaluating pixantrone as a component of first-line, multi-agent regimens also is ongoing in patients with relapsed aggressive NHL. In this trial, pixantrone is used to replace doxorubicin, the anthracycline used in standard treatment regimens for NHL.

Colin Murnane

In 2002, my wife Judy and I were on vacation with several other couples when I discovered a lump on my neck. On our return, I had the lump examined. It turned out to be non-Hodgkin's lymphoma. We couldn't believe it. We were having a house built in Florida. We were planning on moving there from New York and were looking forward to enjoying our retirement playing golf in the sun. But all that had to wait once I was diagnosed with cancer.

Initially, I was treated with a standard regimen of CHOP chemotherapy in combination with rituximab, which seemed to work for a while, but then the cancer came back. I underwent second-line chemotherapy, but I still didn't achieve remission. Finally in late 2005, my doctor suggested that I enter a clinical trial for pixantrone. I went through four cycles of pixantrone treatment and felt really good while I was on it. The pixantrone treatment took much less time than my previous chemotherapy regimens, and the excellent nurses at the Lakeland Center for Cancer Care and Research helped make the hour pass quickly. While on pixantrone, I was able to get back to playing golf — and I even played my best round ever while on pixantrone!

I was very encouraged by the first several CT scans, which suggested the treatment was working. Unfortunately, my cancer appears to be progressing again, so I have started a new chemotherapy treatment. Judy and I remain hopeful that I will achieve remission. We are just taking everything one day at a time.

All I want is to have time to enjoy my retirement with Judy and our wonderful family and friends and to see our beautiful grandson grow up. Judy has been my source of strength through all of this, and we are looking forward to getting on with the plans that we made for our life together. I'm not ready to give up on our dream. I'm glad that I found doctors and nurses who aren't ready to give up either. Even at the age of 65, I still believe I can knock a few strokes off my golf game.



“When I was first diagnosed with non-Hodgkin’s lymphoma, my wife and I were very discouraged about what the future would bring. Today, we feel that with all the treatment options, it’s okay to be more optimistic about our long-term prospects.”

Colin Murnane, pixantrone clinical trial patient (pictured with wife Judy)

To our shareholders:

At Cell Therapeutics, Inc. (CTI), our mission is to make cancer more treatable by developing less toxic and more effective versions of drugs that are the cornerstones of current cancer treatment regimens. In 2005, we refocused our efforts on the development of our most promising product candidates. We are concentrating our assets and resources to advance toward market those drug candidates that we believe will provide the greatest near-term return on our investments while also preserving our long-term growth potential.

Throughout 2005, we remained intent on the prospect of bringing much needed, better treatments for cancer patients as we adapted to the dynamic environment of oncology drug development, ending the year with a refocused strategy and the essential resources to bring our promising products to review and potential approval.

A key objective in 2005 was reporting data from the phase III clinical trial program of XYOTAX™ (paclitaxel poliglumex) in patients with non-small cell lung cancer (NSCLC) and using those data to devise regulatory strategies to support its approval in the United States and Europe. Results of the STELLAR trials demonstrated that XYOTAX as a single agent at 175 mg/m² provides efficacy similar to approved chemotherapeutic agents, with similar or reduced side effects; is easier to administer; and reduces the cost associated with standard therapies. Although the three STELLAR trials did not achieve their overall primary endpoints of improved survival, a significant survival benefit was observed in the STELLAR 3 and STELLAR 4 trials in women treated with XYOTAX, compared to standard chemotherapy.

While the top-line results were unexpected and disappointing, further analyses identified a potential estrogen enhancement of XYOTAX. These data have important implications for the treatment of women with NSCLC and the development of other products based on our polyglutamate technology. In each of these areas, we have allowed the science and the data to drive our course of action.

Based on the compelling data showing a substantial survival advantage in women with PS2 NSCLC treated with XYOTAX, compared with the control chemotherapies, we believe it is our responsibility to make the drug available to this population of patients as expeditiously as possible. In December 2005, we initiated a phase III trial (PIONEER) of XYOTAX as first-line therapy for PS2 women with NSCLC in order to confirm the observed gender-based survival advantage seen in the two STELLAR first-line phase III trials. In February 2006, the U.S. Food and Drug Administration (FDA) confirmed that XYOTAX qualifies for fast track status for the treatment of PS2 women with first-line NSCLC.

Although the results of the STELLAR trials led to an alteration in our initial timeline for submitting the XYOTAX New Drug Application (NDA), we believe that focusing on the gender-specific potential of this novel, biologically enhanced taxane will provide significant benefits to patients while maintaining the drug's commercial potential. Our present target for submission of the NDA is toward the end of 2006 and is timed to have the interim results of the PIONEER trial coincide with our expectation for FDA review. With a favorable review, we anticipate the earliest possible launch of the product in the United States in late 2007. In Europe, we are targeting a submission for XYOTAX in PS2 men and women with NSCLC at the end of 2006, with potential product approval thereafter.

Not only did the XYOTAX gender data drive our clinical and regulatory strategies, they also catalyzed several critical changes in our business and operational infrastructure in 2005. To ensure that we have the financial resources necessary to support our operations as we work toward XYOTAX and pixantrone approval and launch, we reduced our headcount and minimized our facility-related and discretionary operating expenses. We are now positioned to focus our financial and human resources on achieving our near-term objectives: obtaining marketing approval for XYOTAX and completing the pivotal phase III trial of pixantrone in patients with non-Hodgkin's lymphoma (NHL).

With a more flexible and sustainable infrastructure and with significant commercial opportunities ahead, we successfully raised \$82 million through the sale of new convertible debt. In connection with the sale, \$38.4 million in old debt was retired through debt conversions. As a result of these transactions, we strengthened our balance sheet and brought in additional financial resources to fund the advancement of XYOTAX and pixantrone toward the market.

In late 2004, prior to completing the STELLAR trials, we made a strategic decision to divest the TRISENOX® brand in order to concentrate our resources on XYOTAX and pixantrone. In July 2005, we successfully completed the sale of the brand to Cephalon, Inc., for a total of \$71.9 million, net of broker fees, and up to \$100 million in potential future milestone payments, a significant premium to TRISENOX sales.

In 2006, we expect to file for approval of XYOTAX in the United States and Europe, and will continue enrollment in the PIONEER phase III NSCLC trial and the phase III ovarian cancer maintenance trial. We also anticipate conducting an interim analysis of the ongoing phase III pixantrone NHL trial, while continuing to explore the potential of this novel anthracycline in additional indications and treatment regimens.

Longer term, we believe that our polyglutamate polymer technology has significant potential in improving the safety and efficacy of a variety of commonly used chemotherapeutics. Knowledge gained through the STELLAR trials about the impact of estrogen on the metabolism of polyglutamate-conjugated compounds will help to guide the development of CT-2106, which links a camptothecin to the polyglutamate, and other novel therapies based on this technology, which biologically enhances cytotoxic chemotherapy.

We are committed to creating value for patients and for our shareholders. In the months ahead, that commitment will drive all of us at CTI to attain our goals of securing a global partner for XYOTAX and bringing this important therapy to cancer patients in need of new treatment options. Along the way, we will continue to advance pixantrone and CT-2106, manage our financial resources pragmatically, and explore additional opportunities to grow through acquisition.

Our vision is to make cancer more treatable, and I thank you for your support as we work to make that vision a reality.



James A. Bianco, M.D.
President, Chief Executive Officer, and Shareholder



“The results of the STELLAR trials open the door to a new paradigm of gender-specific cancer therapies that address the fundamental biological differences between men and women. From a clinical perspective, this will allow treatment regimens to be optimized to the individual patient.”

James A. Bianco, M.D., President, Chief Executive Officer, CTI

Corporate Directory

Corporate Headquarters

501 Elliott Avenue W., Suite 400
Seattle, Washington 98119
206.282.7100
www.cticseattle.com

Independent Auditors

Stonefield Josephson, Inc.
1620 26th Street, Suite 400 S.
Santa Monica, California 90404

Outside Counsel

Michael J. Kennedy
O'Melveny & Myers, LLP
Embarcadero Center W.
275 Battery Street
San Francisco, California 94111

Registrar and Transfer Agent

Communications concerning transfer requirements, certificate exchanges, lost certificates, changes of address, and name changes should be directed to the Transfer Agent:

Computershare Investor Services
2 N. La Salle Street
Chicago, Illinois 60602
312.588.4187

Investor Relations/ Public Relations

Security analysts, investment professionals, interested investors, and the media should direct their inquiries to:

800.664.CTIC
www.cticseattle.com
invest@cticseattle.com
media@cticseattle.com

Shareholder Inquiries

For questions regarding accounts or to request corporate information, shareholders may write or call:

Shareholder Relations
501 Elliott Avenue W., Suite 400
Seattle, Washington 98119
800.664.CTIC

Stock Information

The Company's initial public offering was March 21, 1997. The Company's common stock trades on the NASDAQ and MTAX stock exchanges under the symbol CTIC.

No dividends have been paid on the common stock to date, and the Company does not anticipate paying dividends in the foreseeable future.

On March 10, 2006, there were approximately 275 holders of record of the Company's common stock.

The following table lists the high and low reported sales prices for the Company's common stock as reported on NASDAQ:

2005		
Quarter	High	Low
1st	\$ 10.85	\$ 3.49
2nd	4.05	2.47
3rd	3.49	1.97
4th	2.83	2.10

Annual Meeting

Detailed information regarding the Annual Meeting will be available on CTI's Web site and in the Proxy Statement.

Directors*

John H. Bauer⁽²⁾
Director
Former Executive Vice President,
Nintendo of America, Inc.

James A. Bianco, M.D.
Director
President and Chief Executive
Officer, Cell Therapeutics, Inc.

Vartan Gregorian, Ph.D.^(1,2,3)
Director
President, Carnegie Corporation

Mary O. Mundinger, D.P.H.^(1,3)
Director
Dean of School of Nursing,
Columbia University

Phillip M. Nudelman, Ph.D.^(1,2,3)
Chair of the Board of Directors
President and CEO,
Hope Heart Institute

Jack W. Singer, M.D.
Director
Executive Vice President and
Chief Medical Officer,
Cell Therapeutics, Inc.

Senior Management Team*

James A. Bianco, M.D.
President, Chief Executive
Officer, and Director

Alberto Bernareggi, Ph.D.
Managing Director,
Cell Therapeutics Europe S.r.l.

Louis A. Bianco
Executive Vice President,
Finance and Administration

Jade Brown
Executive Vice President,
Chief Business Officer

Dan Eramian
Executive Vice President,
Corporate Communications

Jack W. Singer, M.D.
Executive Vice President,
Chief Medical Officer,
and Director

Scott Stromatt, M.D.
Executive Vice President,
Clinical Development and
Regulatory Affairs

Except for the historical information contained herein, the matters set forth in this Annual Report include information concerning our drug development pipeline, including anticipated regulatory timelines and the status of clinical trials, which are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the likelihood of continued efficacy in treatment of cancers with our products, and our ability to successfully develop and support new indications; the impact of technological advances and competition; the timing and ability to enroll and complete clinical trials; the role that other factors and other competitive products may play in accelerating the discovery and development of new therapeutic products; and other risks detailed elsewhere in this report and from time to time in CTI's SEC reports, including its Annual Report on Form 10-K for the year ended December 31, 2005. These forward-looking statements speak only as of the date thereof. CTI disclaims any intent or obligation to update these forward-looking statements.

CTI and XYOTAX (also referred to as CT-2103) are our proprietary marks. All other product names, trademarks, and trade names referred to in this Annual Report are the property of their respective owners.

*As of March 10, 2006

⁽¹⁾ Member of the Compensation Committee.

⁽²⁾ Member of the Audit Committee.

⁽³⁾ Member of the Nominating and Governance Committee.

A Commitment to More Effective Cancer Treatments and Cancer Drugs

As CTI's cancer drugs progress through clinical trials to commercialization, our commitment to patients and the real issues of their cancer treatments grows stronger. The challenge to overcome the therapeutic limitations of cancer treatment provides us with focus and a sense of urgency.



Making cancer more treatable®

www.cticseattle.com