

Many Minds, One Heart

Welcome to CBA Pharma Inc.

The unifying principle of "Many Minds, One Heart"[®] is the core of the philosophical foundation of CBA Pharma. It best reflects the pioneering research and product development successes achieved over the past decade leading to the creation of this company. It signifies the focused intent of many individuals (employees, shareholders, consultants, clinical investigators, etc.) toward a common vision.



Company Info



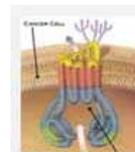
CBA Pharma, Inc. is organized to exclusively manufacture, market, license and distribute to the medical oncology community a drug, CBT-1[®], developed to be an effective treatment for cancer that has developed or may develop drug resistance to chemotherapy.

CBT - 1[®]

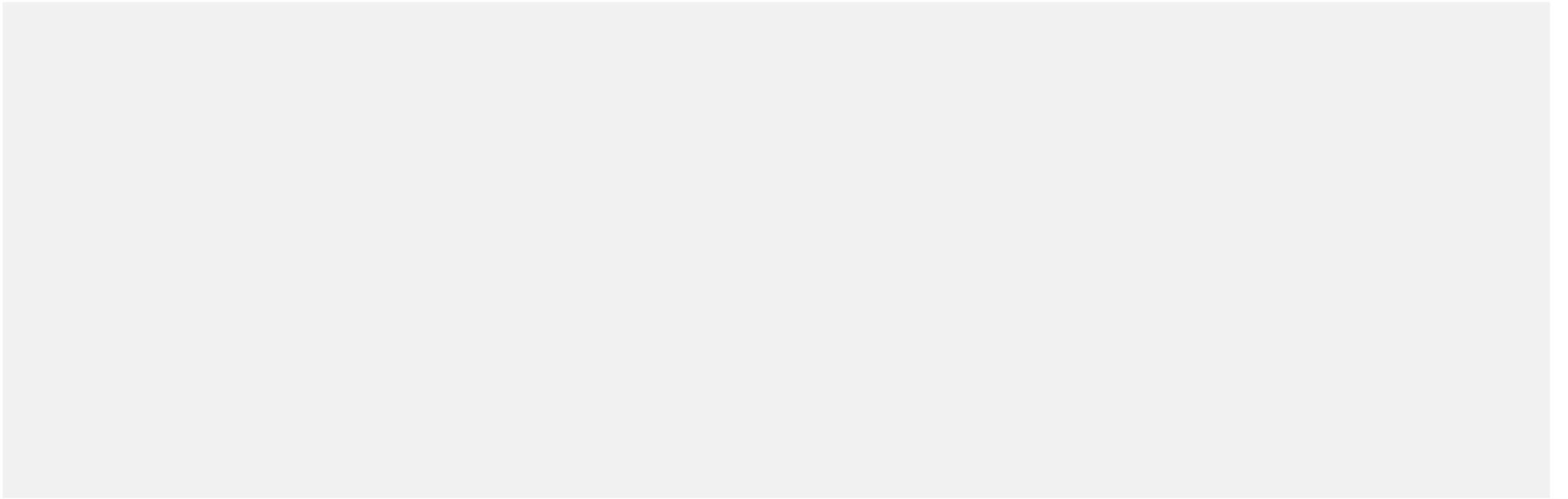


CBT-1[®], taken orally as a pill, was developed to reverse multi-drug resistance in cancer cells and to become part of a Cancer Treatment Program that is administered before a cancer cell can become drug resistant.

Multi-Drug Resistance



(MDR) is the phenomenon whereby cells become resistant to a variety of chemotherapy drugs. Resistance of cancer cells to chemotherapy remains the major cause of treatment failure.



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COMPANY INFO

CBA Pharma, Inc. is a specialty pharmaceutical company headquartered in Lexington, Kentucky.

CBA Pharma, Inc. is organized to exclusively manufacture, market, license and distribute to the medical oncology community a drug, [CBT-1®](#), developed to be an effective treatment for cancer that has developed or may develop drug resistance to chemotherapy.

[Multiple Drug Resistance](#) (MDR) is the phenomenon whereby cells become resistant to a variety of chemotherapy drugs. Resistance of cancer cells to chemotherapy remains the major cause of treatment failure.

CBA Pharma Vision Statement

CBA Pharma's vision is to provide hope and opportunity for a normal life span with an **improved quality of life** to people with life threatening disease.

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"Many Minds, One Heart"®

Our unifying principle means that we, as a company, collaborate the intelligence and creativity of the *minds* in our entire organization and our many alliances toward the single *heartfelt* intent of helping others to heal their disease.

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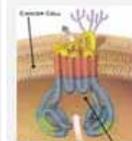
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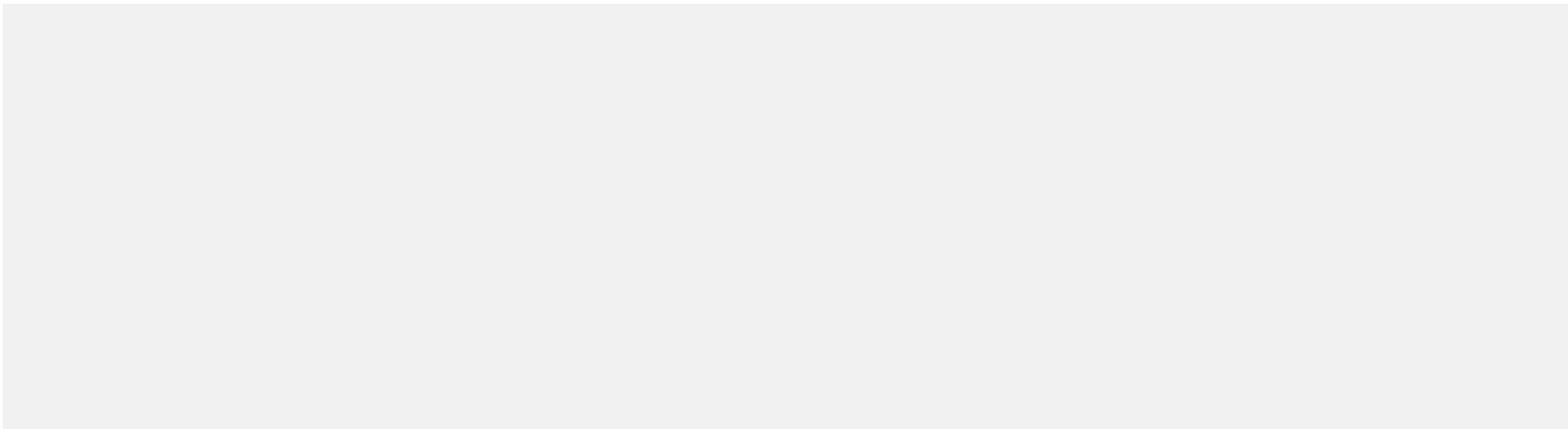


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CBT1[®] Highlights

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CBT-1[®]

CBA Pharma, Inc. has filed the New Drug Application (NDA) for the use of **CBT-1[®]** as an **adjunct to chemotherapy in all cancer types with MDR**. As a lead up to filing the NDA,

CBA Pharma, Inc. **conducted eight clinical trials** to evaluate CBT-1[®] as a MDR modulator. Thirty-eight medical centers or cancer treatment centers participated in clinical trials. Patients were registered with the cancer types of Acute Myelogenous Leukemia, Breast, Non-Hodgkin's Lymphoma, Hodgkin's disease, Non-Small Cell Lung Cancer, Multiple Myeloma, Gallbladder, Pancreatic, Gastrointestinal Tract, Neuroendocrine, Mesothelioma, Small Cell Lung Cancer, Bladder, Head & Neck, Ovarian, Prostrate, and Sarcoma.

Download a CBT-1[®] Presentation [Here](#).

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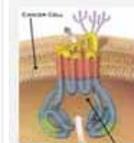
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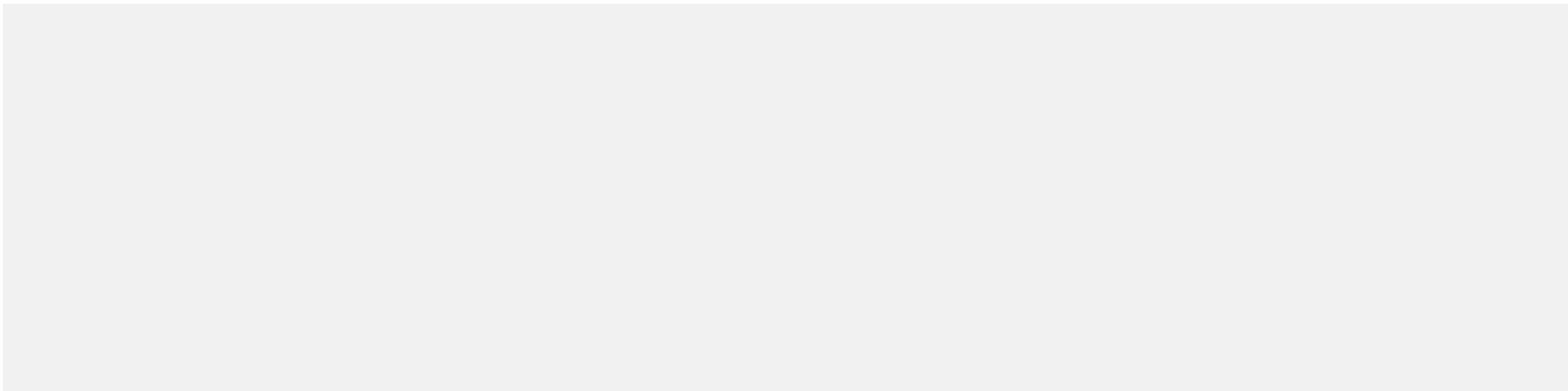


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THE PROBLEM OF MULTIDRUG RESISTANCE

For years it has been known in the medical and pharmaceutical industries that the characteristic that results in the majority of cancer deaths is **multidrug resistance (MDR)** to chemotherapy in relapsed/refractory cancer patients. MDR results in as many as five hundred thousand deaths from cancer annually in the United States alone. Clearly, this is one of the largest **unmet medical needs** for a life threatening disease, with an annual market potential for an effective treatment of MDR in the multiple billions of dollars.

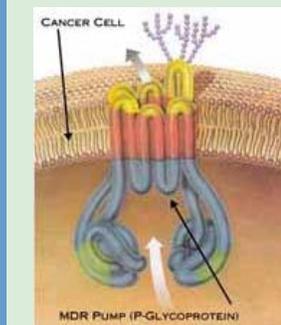
Despite years of costly innovative research and clinical investigation conducted by some of the most reputable cancer centers and pharmaceutical companies worldwide, **no drug or treatment protocol has been approved that safely and effectively sustains modulation of multidrug resistance cancer.** It may require as much as 100 times the acceptable levels of chemotherapy agents to effectively treat patients with MDR in the absence of an MDR Modulator. To date, no drug is available to treat relapsed/refractory cancer patients that are drug resistant to chemotherapy.

Tumor of average detectable size contains hundreds of millions of cells, some are likely to be drug resistant.

Treatment with chemotherapy (even combinations) may result in response or remission, yet the drug resistant cells and their progeny continue to multiply.

Eventually, drug resistant cancer cells dominate and continue to multiply, resulting in death.

Mechanisms that promote MDR in cancer cells include multidrug resistance casually associated with glutathione-s-transferase and topoisomerase I/II isoenzymes as well as more intensively studied MDR-1, MRP-1, LRP and ACGG2 proteins. The P-glycoprotein (Pgp) pump and MDR-1 encoded membrane, is one of the most prevalent and well documented causes of MDR. The Pgp pump, a member of the super family known as ATP-binding cassettes (ABC), acts as an efflux transporter that lowers intracellular concentration of multiple chemotherapeutic agents, thus creating MDR. What has been needed to solve the MDR problem is an MDR Modulator that inhibits the MDR pumps, especially the Pgp and MRP-1 pumps.



Drug resistance pump inside a cancer cell (Above). Click to see a [Flash animation](#) of CBT-1[®] in action! (77k)

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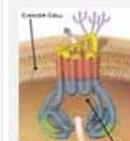
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CONTACT US

For shareholder questions or information contact David Williams at:
br549@cba-1.com

For questions about the website please contact the webmaster at:
webmaster@cba-1.com

CBA Pharma, Inc.
670 Perimeter Drive
Lexington, KY 40517

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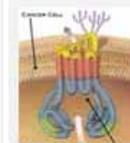
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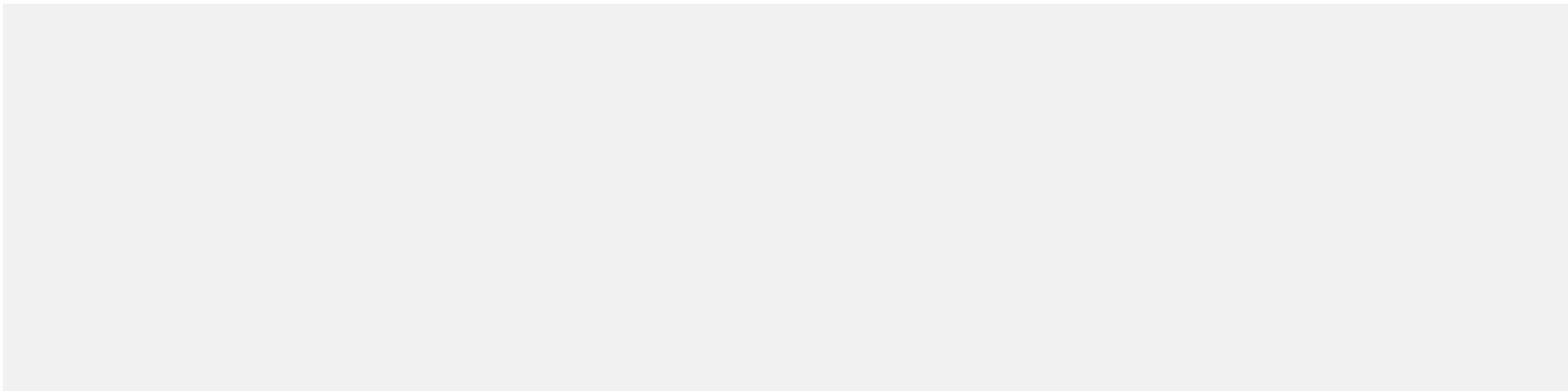


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NEWS

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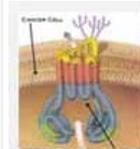
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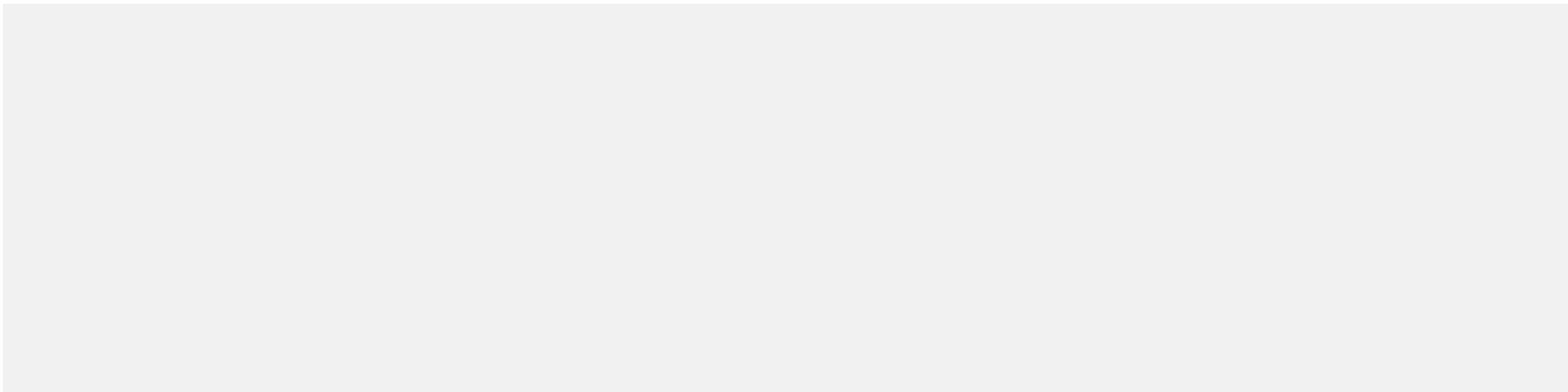


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The CBAPharma.com websites may provide links to third-party websites for your convenience and information. If you access those links, you will leave the CBAPharma.com website. CBAPharma.com does not control those sites or their privacy practices, which may differ from CBAPharma.com's. We do not endorse or make any representations about third-party websites. The personal data you choose to give to unrelated third parties is not covered by the CBAPharma.com Privacy Statement. We encourage you to review the privacy policy of any company before submitting your personal information. Some third-party companies may choose to share their personal data with CBAPharma.com; that sharing is governed by that third-party company's privacy policy.

2. Types of information we collect

This Privacy Statement covers personal information, non-personal data collection and aggregate reporting.

- **PERSONAL INFORMATION**
is information that is associated with your name or personal identity. Once you choose to provide us with personal information, you can be assured it will be used only to support your relationship with CBAPharma.com. We take seriously the trust you place in us. CBAPharma.com will not sell, rent or lease your personal information to others.
- **NON-PERSONAL INFORMATION**
is data about usage and service operation that is not associated with a specific personal identity. CBAPharma.com collects and analyzes non-personal information to evaluate how visitors use the CBAPharma.com websites.

Non-personal data we collect may include the pages visited on the CBAPharma.com websites, unique URLs visited within CBAPharma.com, browser type and IP address. Most non-personal data is collected via cookies or other analysis technologies. CBAPharma.com Web pages may use cookies, Web beacons and other technologies for data analysis and personalization services. CBAPharma.com also may place ads on other websites that may use cookies.

3. How we use your information

CBAPharma.com uses your personal information to help to communicate with you. Occasionally we may also use your information to contact you. We will give you the opportunity to choose your privacy preferences regarding such communications (see section 7, "Your privacy preferences and opting out").

Personal data collected online may also be combined with information you provide CBAPharma.com through other sources such as product registration, call centers or public events such as trade shows or seminars.

Personal data given to CBAPharma.com may be transferred across state and country borders for the purposes of data consolidation, storage and simplified customer information management.

Non-personal data is aggregated for reporting about CBAPharma.com website usability, performance and effectiveness. It is used to improve the customer experience, usability and site content.

5. WHO WE SHARE YOUR INFORMATION WITH

CBAPharma.com will not sell, rent or lease your personal information to others. CBAPharma.com will not share your personal information with third parties except in responding to your requests for products or services. Your permission will be requested when you submit your information. CBAPharma.com shares customer information across CBAPharma.com-owned business entities and companies working on our behalf, but only as described above in "How we use your information."

CBAPharma.com contracts with third-party service providers and suppliers to deliver services and customer solutions described in "How we use your information." Suppliers and service providers are required to keep confidential the information received on behalf of CBAPharma.com and may not use it for any purpose other than to carry out the services they are performing for CBAPharma.com. These service providers may change or we may contract with additional service providers to better accommodate our customers. CBAPharma.com will not share personal information with any other third parties without your permission, unless required by law enforcement action, subpoena, or local law.

CBAPharma.com or its related entities could merge with or be acquired by another business entity or some or all of their respective assets could be acquired. If such a combination or acquisition occurs, CBAPharma.com will make every reasonable effort to notify you in the event we share with the merging or acquiring entity some or all of your personal information to continue serving you.

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To opt-out of receiving communications you have expressly requested (such as newsletters, phone calls, etc.), use any of the following methods:

- Write to the [CBAPharma.com Webmaster](#) - be sure to provide your name, e-mail and postal address, and relevant information about your CBAPharma.com communications
- Call the phone number provided on any correspondence materials sent previously and make the request of the Office of Shareholders

8. Your information and third-party companies

Certain CBAPharma.com services maybe linked with those from unrelated third-party companies. We will not share your personal information with those third-party companies unless you make that choice.

9. Access to and accuracy of your information

CBAPharma.com strives to keep your personal information accurate. We have implemented technology, management processes and policies to maintain customer data accuracy.

The most effective way to view and change your personal information is to return to where you originally submitted your data and resubmit the data accurately.

10. Keeping your information secure

CBAPharma.com is committed to protecting the information you provide us. To prevent unauthorized access or disclosure, to maintain data accuracy, and to ensure the appropriate use of the information, CBAPharma.com has in place appropriate physical

and managerial procedures to safeguard the information we collect.

11. CHANGES TO THIS STATEMENT

If there are updates to the terms of CBAPharma.com's Online Privacy Statement, we will post those changes and update the revision date in this document, so you will always know what information we collect online, how we use it, and what choices you have.

12. Contacting us

We value your opinions. If you have comments or questions about our privacy policy, please send them to the [CBAPharma.com Webmaster](mailto:CBAPharma.com) or write to us at the following address:

CBAPharma, Inc.
670 Perimeter Drive
Lexington, KY 40517

Rev. Feb. 2006

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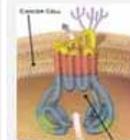
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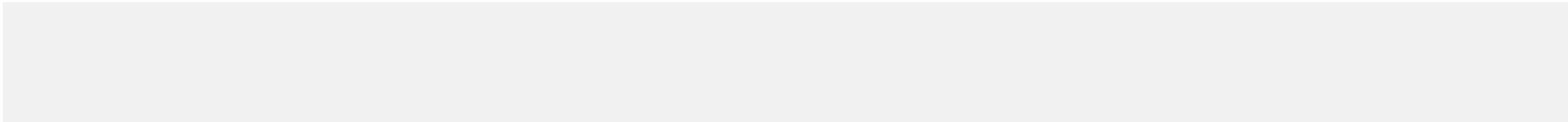


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Revised October 2012

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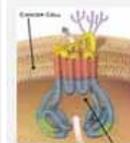
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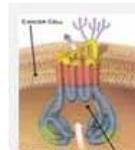
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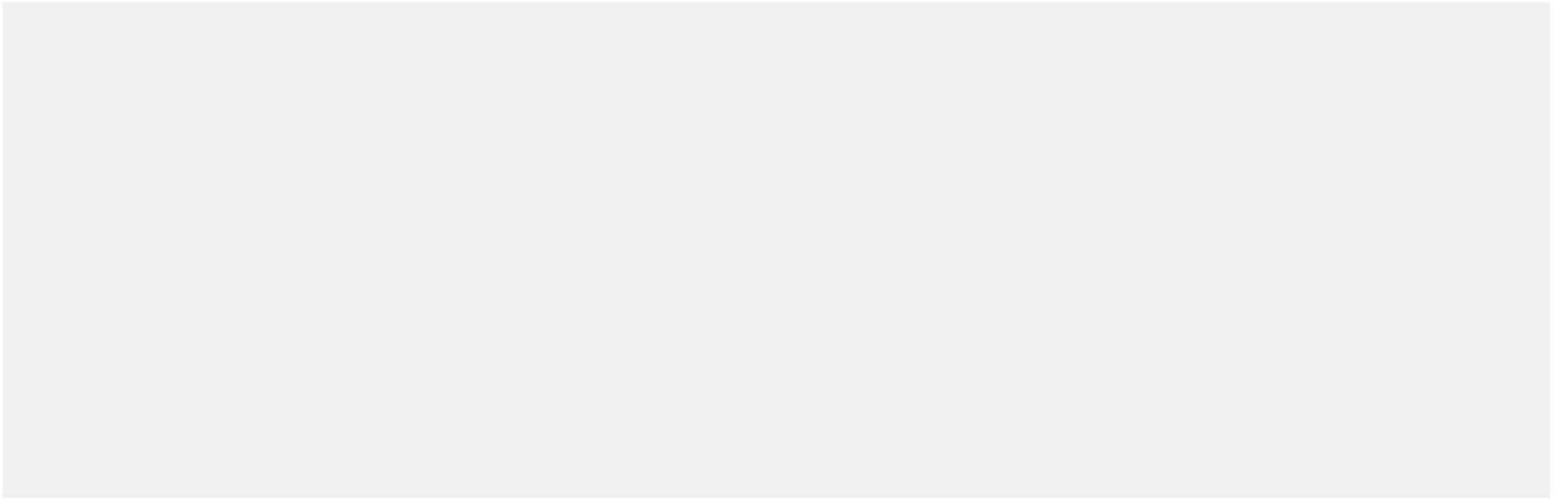


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CBT-1 HIGHLIGHTS

HIGHLIGHT	DESCRIPTION
NEW DRUG APPLICATION SUBMITTED	CBA Pharma, Inc. has submitted its New Drug Application (NDA) to the FDA for the use of CBT-1® as an adjunct to chemotherapy in all cancer types. Result of 22 years of basic science, animal and human research, including 18 years of clinical trials. Tested at 38 leading cancer treatment centers in 21 states.
RESISTANT MODULATION	CBT-1® has demonstrated the potential in preclinical and clinical trials to be an effective treatment for cancer that exhibits multidrug resistance (MDR) to chemotherapy as a multidrug resistant modulator
UNMET MEDICAL NEED; LIFE-THREATENING DISEASE	Multidrug resistance in cancer is responsible for a majority of cancer deaths, and to date there is no FDA approved treatment for it.
SMALL MOLECULE	CBT-1® is a small stable molecule with broad pharmacological effect.
STABLE PHARMOCKINETICS	CBT-1® has proven in clinical trials to not significantly alter the pharmacokinetic profile of chemotherapy agents.
ADMINISTERED ORALLY	Oral delivery of CBT-1® prior to and during the administration of chemotherapy, achieves the required therapeutic concentration necessary to reverse multidrug resistance in the clinical setting
NO SIGNIFICANT OR LASTING TOXIC SIDE EFFECTS	CBT-1® demonstrated no significant or lasting side effects in the clinical setting, and had a very favorable adverse event profile.
MULTIPLE CHEMOTHERAPY AGENTS	CBT-1® has demonstrated in preclinical and clinical trials the potential to enhance the effectiveness of leading chemotherapy agents when multidrug resistance occurred. Various substrates for MDR have tested positive including Doxorubicin, Vineristine, Vinblastine, Etoposide, Daunorubicin, Mitoxantrone, Taxol, Paclitaxel, and Carboplatin.
NATIONAL CANCER INSTITUTE	CBA Pharma, Inc. has collaborated with the National Cancer Institute in preclinical and clinical studies for multiple cancer types, and is working toward a clinical trial for AML (acute myelogenous leukemia).
MULTIPLE CANCERS	Eight Phase I and II clinical trials, with patients that had failed conventional chemotherapy treatments, showed

efficacy of CBT-1[®] in multiple cancers. Likewise, the targeted mechanism of action multidrug resistance of CBT-1[®] is found in the vast majority of all late stage human cancer types.

HIGH PATIENT BENEFIT IN PHASE I AND II CLINICAL TRIALS

CBT-1[®] has demonstrated in Phase I and II clinical trials a high rate of patient benefit. Depending on the cancer type and stage, as much as 70% or greater patient benefit was demonstrated.

ADJUNCT TO EXISTING ONCOLOGY PROTOCOLS

The administration of CBT-1[®] fits within the current oncology protocols and does not replace them, and thereby invites the potential for more rapid acceptance by the medical oncology community.

POTENTIAL COST REDUCTION

The treatment of multidrug resistance with CBT-1[®] as an adjunct therapy provides for the potential of major cost reduction in patient and third party costs.

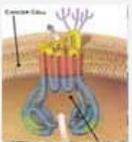
POTENTIAL LOWER CHEMOTHERAPY DOSAGES

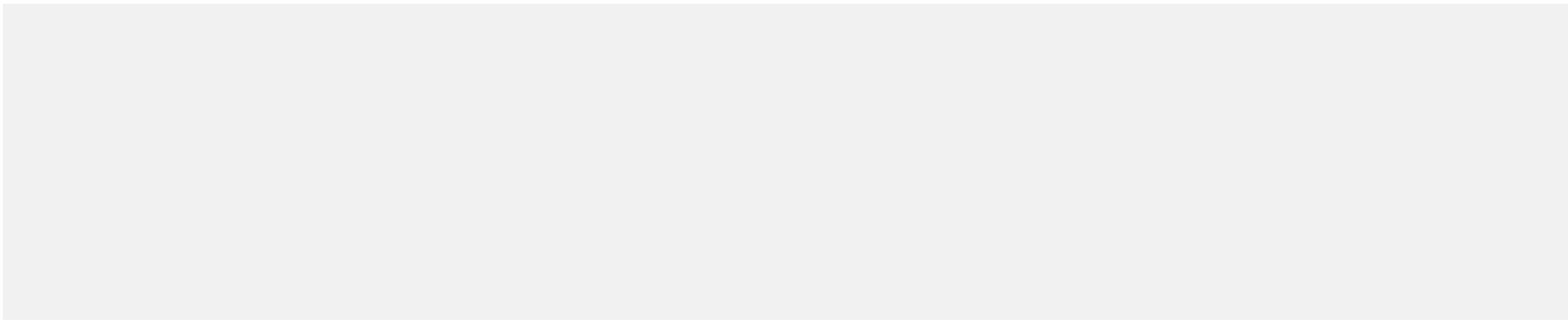
In vitro studies demonstrated that lowering chemotherapy dosages with CBT-1[®] does not lower efficacy. Additionally, CBT-1[®] demonstrated increased cellular chemotherapy retention and increased cellular uptake in freshly acquired cancer patient specimens. This opens the door for reduction in side effects from chemotherapy, subject to further human clinical trials.

PATENTS

Patents and patents pending provide a broad defensible legal framework to protect CBT-1[®] in the marketplace.

Please click [Terms and Conditions](#) link below for forward looking statements disclosures, limitations, disclaimers and risk factors regarding the above CBT-1[®] Highlights.

<p>Company Info</p>	<p>CBT - 1[®]</p>	<p>Multi-Drug Resistance</p>
 <p>CBA Pharma, Inc. is organized to exclusively manufacture, market, license and distribute to the medical oncology community a drug, CBT-1[®], developed to be an effective treatment for cancer that has developed or may develop drug resistance to chemotherapy.</p>	 <p>CBT-1[®], taken orally as a pill, was developed to reverse multi-drug resistance in cancer cells and to become part of a Cancer Treatment Program that is administered before a cancer cell can become drug resistant.</p>	 <p>(MDR) is the phenomenon whereby cells become resistant to a variety of chemotherapy drugs. Resistance of cancer cells to chemotherapy remains the major cause of treatment failure.</p>



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CBT-1[®] PRECLINICAL

Assay/Test Method

Description

Results

<u>Assay/Test Method</u>	<u>Description</u>	<u>Results</u>
MTT	Cytotoxic assay	Complete modulation
XTT	Cytotoxic assay	Complete modulation
Flow Cytometry	Flourescence	
	Inhibition/ efflux	
	-Rhodamine 123	Complete Inhibition
	-Calcein	Complete Inhibition
	-In Vivo CDX 56	Complete Inhibition

MDR Protein substrates combined CBT-1[®] In Vitro & In Vivo

Doxorubicin	Mitoxantrone	Vinblastine	Vincristine
Etoposide	Taxol	Carboplatin	Daunorubicin
Cytosine	arabinoside	Calcein	Rhodadime 123
Depsipeptide	99M TC-sestamibi	-	-

[In Vitro Analysis With Doxorubicin \(click for chart\)](#)

Company Info



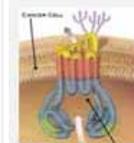
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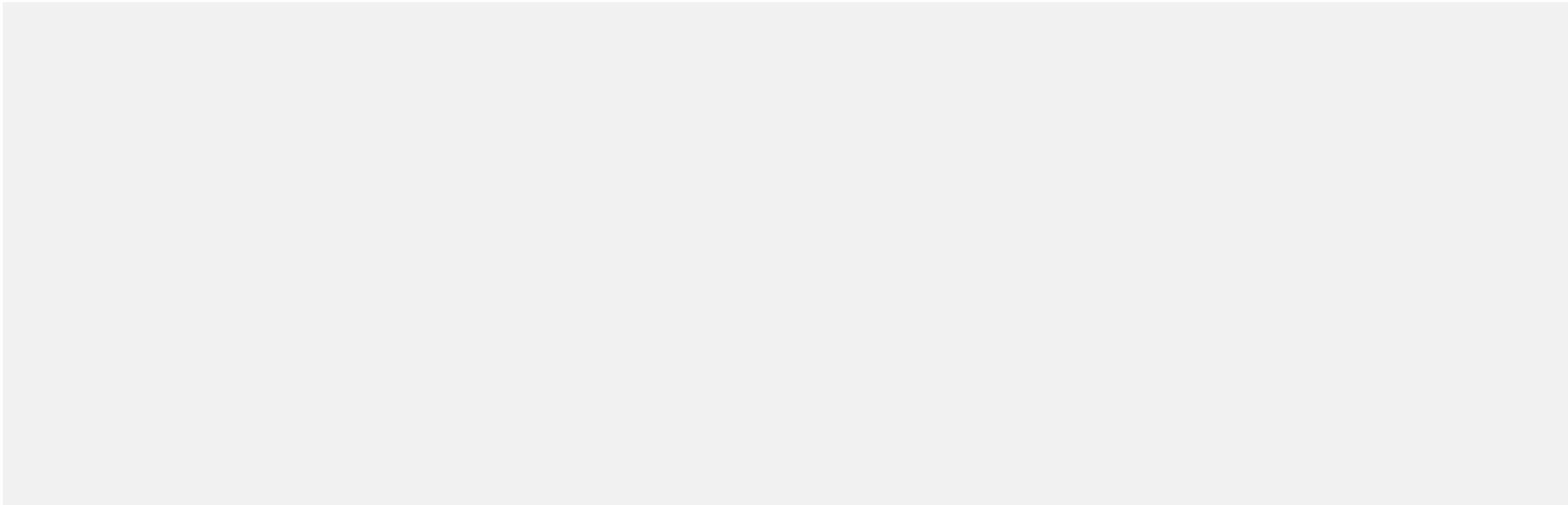


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CBT-1[®] CLINICAL TRIALS

Please Click below to review the contents regarding each Phase of Clinical Trials

[PHASE I](#)

[PHASE II](#)

[PHASE III](#)

Download a CBT-1[®] Presentation [Here](#).

Company Info



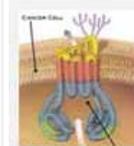
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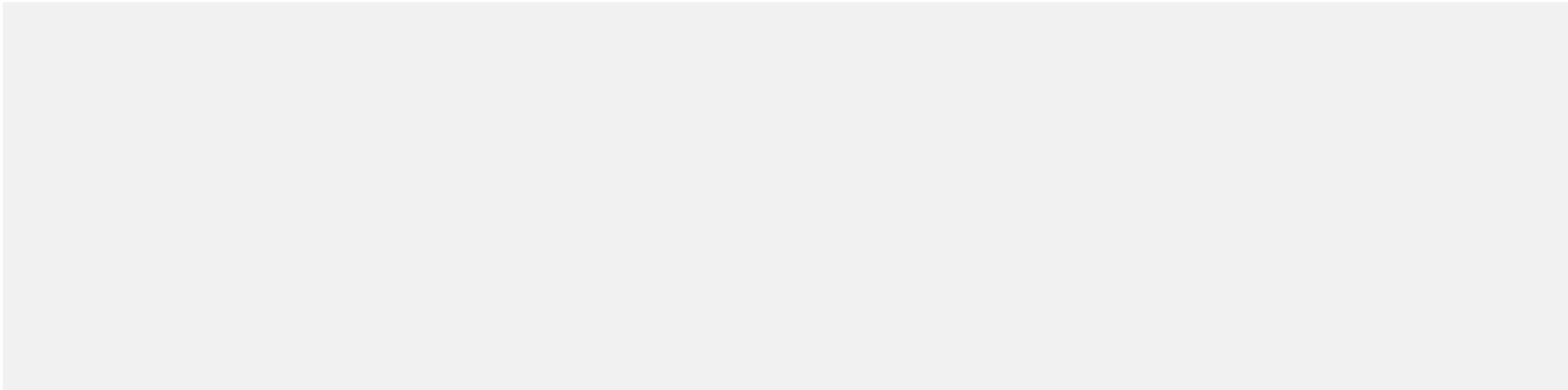


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CBT-1[®] CLINICAL TESTING AS MDR MODULATOR

Phase I

Phase I in patients failing first line therapy using concurrent **Doxorubicin** at several dosage levels designed to determine maximum tolerable dose in combination with fixed dose of Doxorubicin and pharmacokinetic interaction.

Phase I with **Paclitaxel** in patients who had failed first line therapy, including Paclitaxel. Two additional patients entered on separate arm to study pharmacokinetic interaction.

Phase I study in combination with Paclitaxel and Carboplatin in unresectable NSCLC.

Phase I study in combination with Paclitaxel and Doxorubicin in advanced unresectable breast cancer.

Company Info



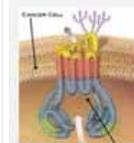
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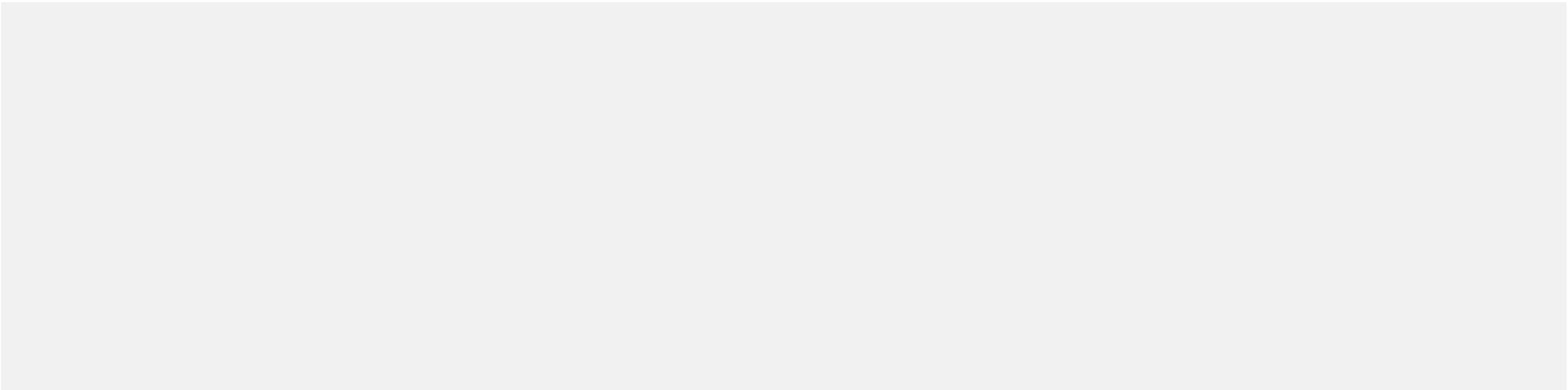


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CBT-1[®] CLINICAL TESTING AS MDR MODULATOR

Phase II

Phase II study with high dose Cytosine Arabinoside and Daunorubicin in multiple relapsed or refractory AML

Phase II with Paclitaxel in various advanced relapsed cancers including GI, multiple myeloma, breast, SCLC, NSCLC, ovarian, prostate, cervical and head&neck.

Phase II Pharmacodynamic study of CBT-1[®] and Paclitaxel evaluating PGP inhibition in tumor and normal tissue conducted in collaboration with the NCI.

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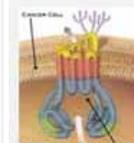
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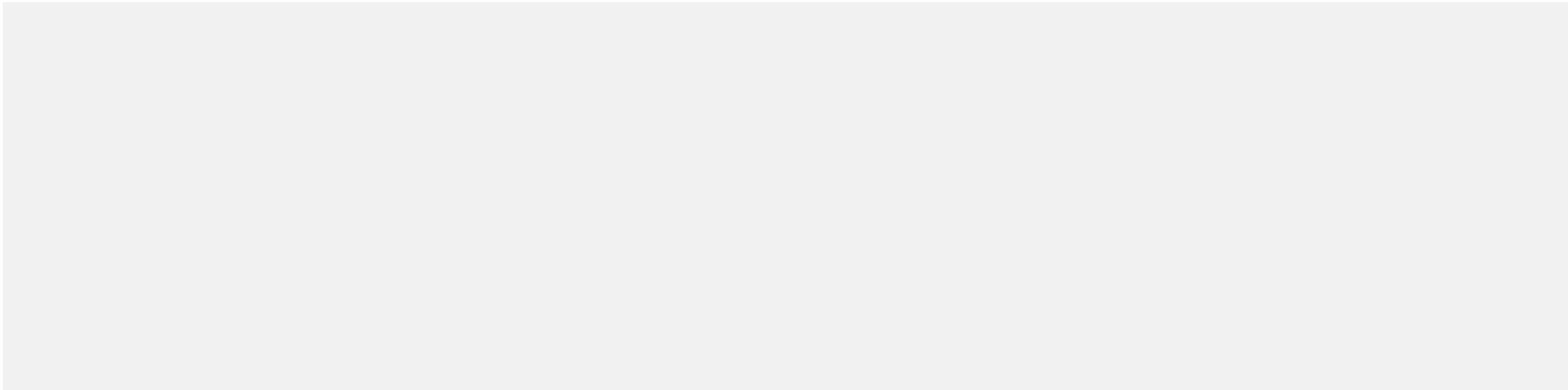


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CBT-1[®] CLINICAL TESTING AS MDR MODULATOR

Phase III

Placebo controlled randomized study of CBT-1[®] Paclitaxel and Carboplatin in NSCLC.

Company Info



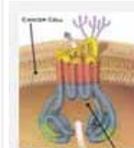
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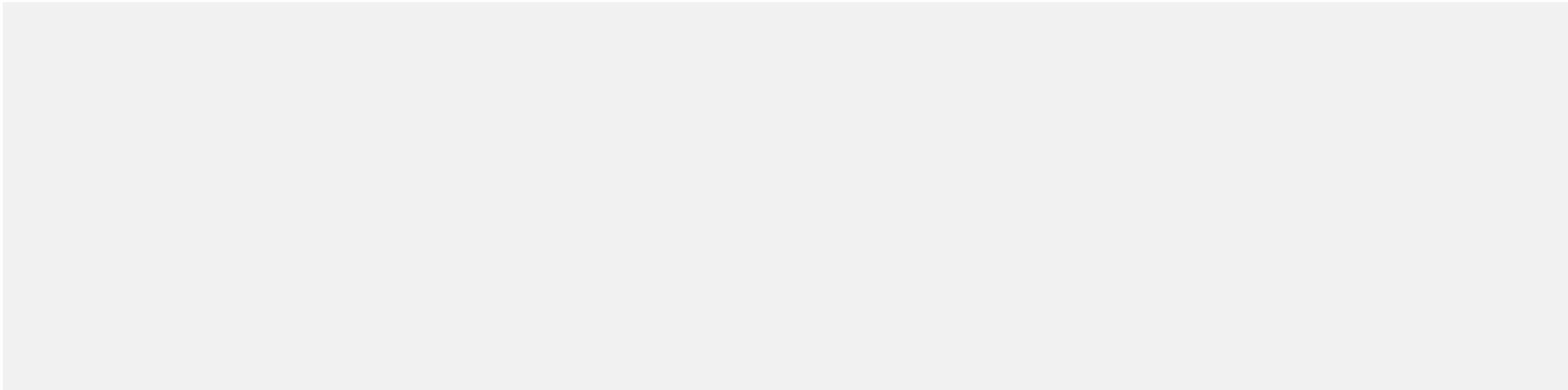


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CBT-1[®] PUBLICATIONS

Publications:

Kelly, R. J., Robey, R. W., Chen, C. C., Draper, D., Luchenko, V., Barnett, D., Oldham, R. K., Caluag, Z., Frye, A. R., Steinberg, S. M., Fojo, T., Bates, S. E., [A Pharmacodynamic Study of the P-glycoprotein Antagonist CBT-1[®] in Combination With Paclitaxel in Solid Tumors](#), 2012, *The Oncologist*, 17, 2012-0080

Robey, R. W., Shukla, S., Finely, E. M., Oldham, R. K., Barnett, D., Ambudkar, S. V., Fojo, T., Bates, S. E., [Inhibition of P-glycoprotein \(ABCB1\)-and Multidrug Resistance-Associated Protein 1 \(ABCC1\)-Mediated Transport By The Orally Administered Inhibitor, CBT-1[®]](#), 2008, *Biochemical Pharmacology*, 75, 6, 1302-1312

Oldham, R. K., Reid, W. K., and Barnett, D., [Phase I Study of CBT-1[®] and Taxol[®] in Patients With Taxol[®] Resistant Cancers](#), 2000, *Cancer Biotherapy & Radiopharmaceuticals*, 15, 153-159

Oldham, R. K., Reid, W. K., Preisler, H. D., and Barnett, D., [A Phase I Pharmacokinetic Study of CBT-1[®] as a Multidrug Resistance Modulator in the Treatment of Patients With Advanced Cancer](#), 1998, *Cancer Biotherapy & Radiopharmaceuticals*, 13, 71-80

Poster Presentation:

New England Science Symposium; Oral Presenter Elizabeth Finely; Robey, R., Bates, S., Fojo, T., Barnett, D., Oldham, R., Polgar, O., Orbzut, T., Ediriwickrema, L.; [The Natural Product CBT-1[®] Inhibits Pgp and MRP1-Mediated Drug Resistance](#); 2007

AAPS National Biotechnology Conference; Robey, R., Shukla, S., Finely, Oldham, R., Barnett, D., Ambudkar, S., Fojo, T., Bates, S.; [The Natural Product CBT-1[®] Inhibits Pgp and MRP1-Mediated Drug Resistance](#); 2007

International Lung Cancer Conference; Oldham, R.K., Barnett, D., Ramos, Z.; [A Phase II Study of Taxol[®]/CBT-1[®], an MDR Modulator](#); 2002

Abstracts:

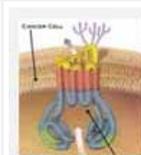
American Society of Clinical Oncology (ASCO); Oldham, R.K., Barnett, D., Ramos, Z.; [A Phase II Study of Paclitaxel/CBT-1[®], an MDR Modulator](#); 2003



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ROBERT K. OLDHAM M.D. MEDICAL DIRECTOR & VICE PRESIDENT OF BUSINESS DEVELOPMENT



Dr. Robert K. Oldham is an internationally recognized cancer specialist and is regarded as a leading pioneer in the development and use of biotherapy - the fourth modality in cancer treatment. He is Director of the Lower Keys Cancer Center.

Dr. Oldham attended the University of Missouri at Columbia where his undergraduate studies were in chemical engineering and pre-medical sciences. He completed his M.D. degree in 1968. During medical school, he was awarded two PHS Cancer Clinical Research Fellowships. Dr. Oldham subsequently interned and did his residency in Internal Medicine at the Vanderbilt University Hospital in Nashville. He continued his education with a Medical Oncology Fellowship and graduate studies in immunology at the National Cancer Institute (NCI) in Bethesda, Maryland during 1970-1972. There he served as Clinical Associate in the Radiation Branch and in the Cellular and Tumor Immunology Section of the Laboratory of Cell Biology.

Research and active leadership in cancer treatment has been the ongoing focus of Dr. Oldham's professional life. He left the National Cancer Institute in 1972 to serve as Research Associate with Professor G. Mathe' at Hospital Paul Brousse in Villejuif, France, then returned as Senior Investigator in the National Cancer Institute's Cellular and Tumor Immunology Section of the Laboratory of Immunodiagnosis during 1973-1975. From 1975-1980 he served as Associate Professor of Medicine and Associate Director of the Vanderbilt Cancer Center where he also was Founder and Director of the Division of Oncology. Dr. Oldham returned to the National Cancer Institute from 1980-1984 to serve as Associate Director of the Division of Cancer Treatment and as Founding Director of the Biological Response Modifiers Program. In 1984, Dr. Oldham established the Biomedical Research Center at the University of British Columbia (Founder and Consultant). Later he founded the Biological Therapy Institute and Biotherapeutics Incorporated (Founder, Scientific Director and Chairman of the Board) in Franklin, TN. Since then, he has also served as Chairman of the Board for Media America, Chairman of the Board and President of American Patient Services and Chairman of the Board and CEO of Cancer Therapeutics Incorporated. He holds a Clinical Professorship of Medicine in Hematology/Oncology at the University of Missouri-Columbia and has been a Clinical Professor in the Department of Biomedical Sciences at Florida State University College of Medicine. Dr. Oldham currently serves as consulting Medical Director and Vice President for Business Development for CBA Research in Lexington, Kentucky.

Dr. Oldham has received several NCI clinical group appointments including the Lung Cancer and Southeastern Oncology Study Groups. He was the Founder and President of the Society for Biological Therapy and was Founder and Chairman of the National Biotherapy Study Group. He has also acted as consultant to various companies in the US and abroad such as Gen-Cell (Rhône-Poulenc), Jenner Technologies, Wellcome Biotechnology Ltd. and Amersham Corporation in England. More recently, he has been a senior consultant with the American Red Cross, Cell Genesys Inc., Xcyte Therapies and Maxim Pharmaceuticals. Dr. Oldham is the

founder and has served as editor-in-chief of three medical journals: Cancer Biotherapy (now Cancer Biotherapy & Radiopharmaceuticals), Molecular Biotherapy, and Journal of Biological Response Modifiers (now Journal of Immunotherapy). He is the co-editor of Principles of Cancer Biotherapy' the first comprehensive textbook on the fourth modality of cancer treatment and has authored or edited fifteen books on cancer treatment and research. Additionally, he has contributed over 400 papers to the medical/scientific literature and has presented thousands of abstracts, posters, and lectures at various meetings on cancer research and treatment. Dr. Oldham has received many awards and honors. He holds or has held membership and in 19 professional societies.

Dr. Oldham's primary mission has been to improve the outcomes for his patients with cancer and blood disorders.

Company Info



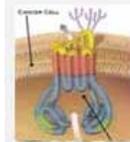
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CBA PHARMA MOVING FORWARD

As of the second quarter of 2012, the Board of Directors of CBA Pharma, Inc. decided it was in the best interest of the Company to seek one or more large pharmaceutical partners to complete the NDA process with the FDA and commercialize CBT-1® in the United States and/or international markets.

Company Info



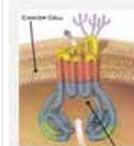
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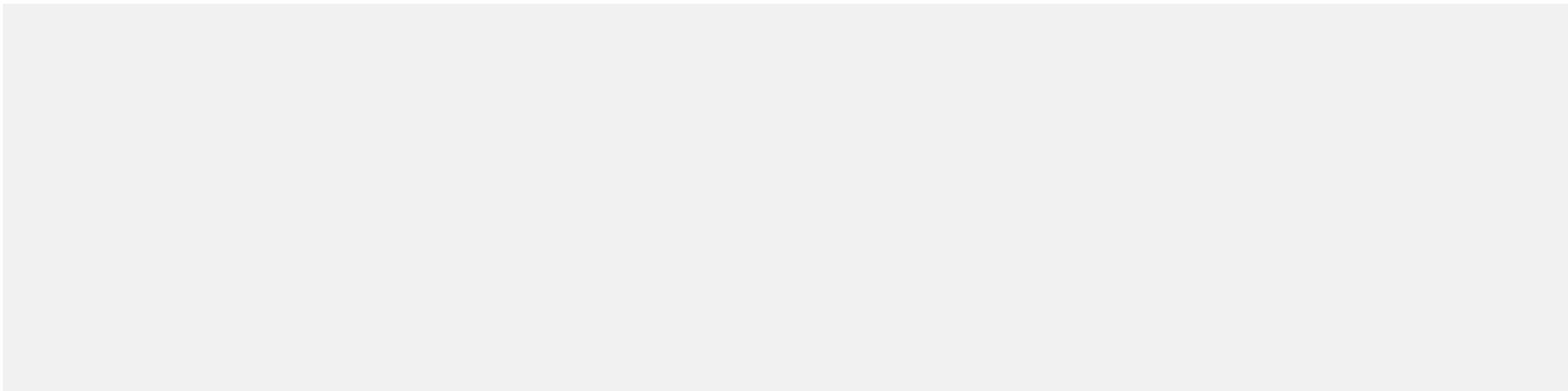


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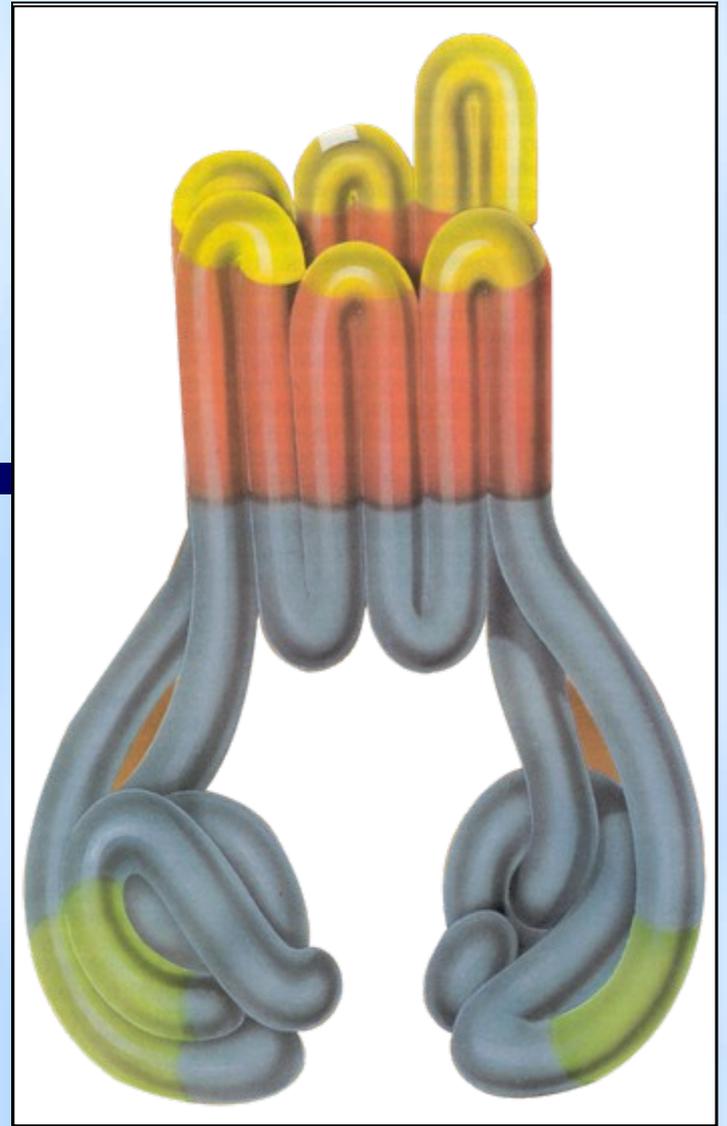
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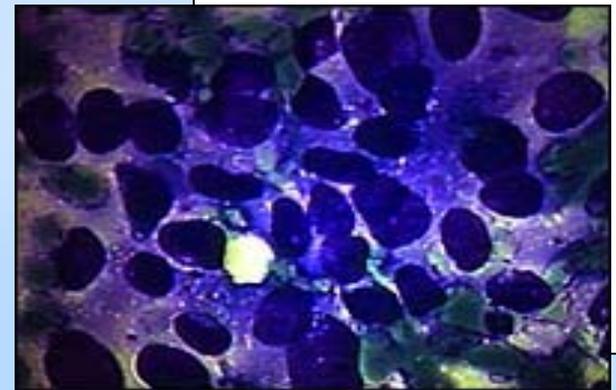
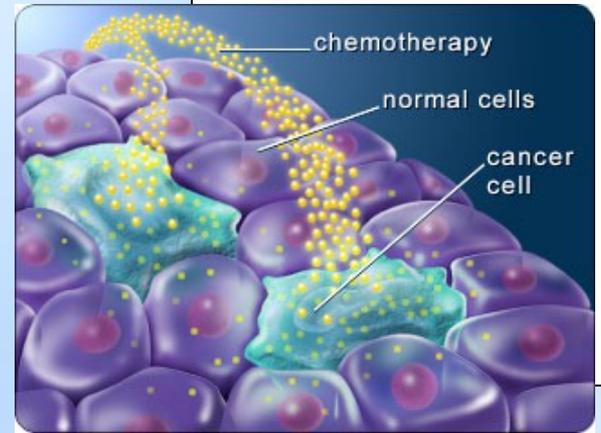
**A Novel Multidrug Resistant Modulator
for Cancer Chemotherapy**

CBA Pharma, Inc.



CBT-1[®] Highlights

- **Developed as a treatment for cancer that exhibits multidrug resistance to chemotherapy**
- **22 years of basic science, animal and human research, including 18 years of clinical trials**
- **Tested at 38 leading cancer treatment centers in 21 states**

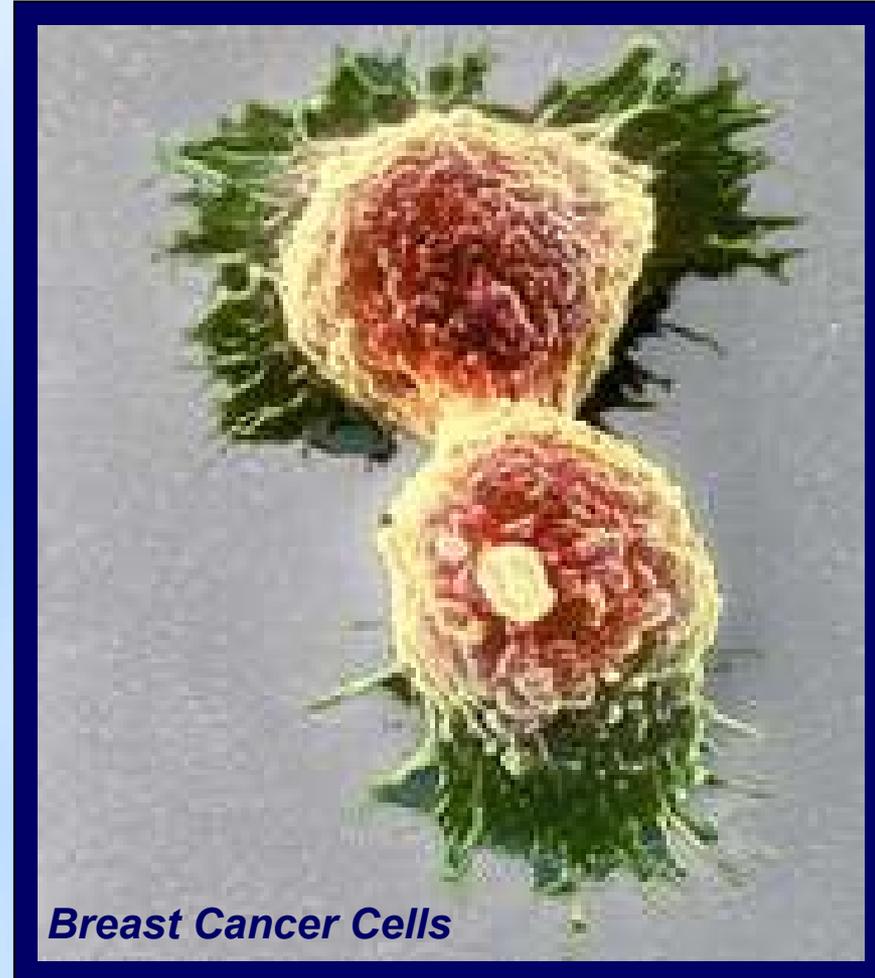


Multidrug Resistance

- **Tumor of average detectable size contains hundreds of millions of cells, some are likely to be drug resistant.**
- **Chemotherapy treatment (even combinations) may result in response or remission, yet drug resistant cells and their progeny continue to multiply.**
- **Eventually drug resistant cancer cells dominate and continue to multiply, resulting in death.**

Multidrug Resistance (MDR) In Cancer Chemotherapy

- MDR occurs when cells display or develop a resistance to a variety of chemotherapy drugs.
- Resistance to chemotherapy in cancer cells remains the major cause of treatment failure.
- Many forms of MDR cancer result from a gene that produces a cell-membrane based protein called (P-glycoprotein).



Hypotheses of Causes of MDR

- **Increased expression of the MDR1 P-gp170 (ABCB1), a glycoprotein in the plasma membrane of the cell.**

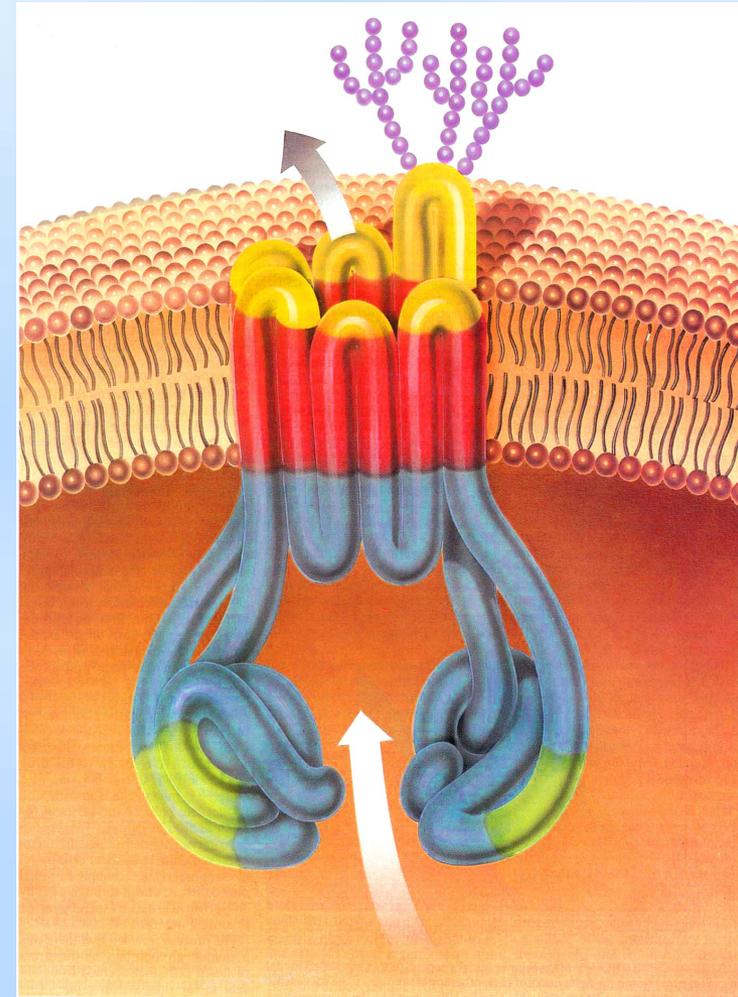
A number of agents have been identified that can interfere with ability of P-gp170 glycoprotein to pump chemotherapeutic agents from the cell, clinical utility has been limited by toxic levels required to affect pump Inhibition (eg. Verapamil).

- **Increased expression of a 2nd and 3rd ABC transporter, MRP1, ABCG2.**

P-gp 170 (ABCB1), MRP1 (ABCC1) and BCRP (ABCG2) are members of a super-family referred to as ATP-binding cassettes (ABC) which are energy dependent trans-membrane pumps. These pumps function as efflux transporters which excrete intracellular toxins such as cytotoxic drugs making the cell less susceptible to the drug's toxic actions.

P-Glycoprotein Model

- P-Glycoprotein resides in the cell membrane.
- Model of the protein chain believed to snake back and forth across the lipid bi-layer of the membrane forming a 12 sided pore.
- The pan of the protein outside the cell bears sugar chains (purple).
- The two blue/green domains protrude into the cell and include regions (green) that bind cellular energy carrying compound ATP, which probably provides the energy that drives the efflux (arrows).



National Cancer Institute (NCI) Collaboration

- **NCI team includes world leading scientists in cancers that have developed multidrug resistance to chemotherapies.**
- **Collaborating on development of CBT-1[®] for over 5 years.**
- **Performed and published independent in vitro CBT-1[®] studies.**
- **Performed and published on Phase II clinical trial for CBT-1[®].**

CBT-1[®] Clinical Tests

Chemotherapies tested:

Doxorubicin

Daunorubicin

Carboplatin

Paclitaxel

Cytosine Arabinoside

CBT-1®

Clinical Cancers Tested:

- **Breast**
- **Ovarian**
- **Uterine**
- **Multiple Myeloma**
- **Gastrointestinal**
- **Small Cell Lung**
- **Pancreatic**
- **Acute Myelogenous Leukemia**
- **Non-Small Cell Lung**
- **Cervical**
- **Head & Neck**
- **Prostate**
- **Sarcoma**
- **Bladder**
- **Hodgkins and Non-Hodgkins Lymphoma**

CBT-1[®] Preclinical

Assay/Test Method	Description	Results
MTT	Cytotoxic assay	Complete modulation
XTT	Cytotoxic assay	Complete modulation
Flow Cytometry	Flourescence Inhibition/ efflux	
	-Rhodamine 123	Complete Inhibition
	-Calcein	Complete Inhibition
	-Ex Vivo CD 56 ⁺	Complete Inhibition

MDR Protein substrates combined with CBT-1[®] In Vitro & In Vivo

Doxorubicin

Daunorubicin

Mitoxantrone

Cytosine arabinoside

Vinblastine

Calcein

Vincristine

Rhodadime 123

Etoposide

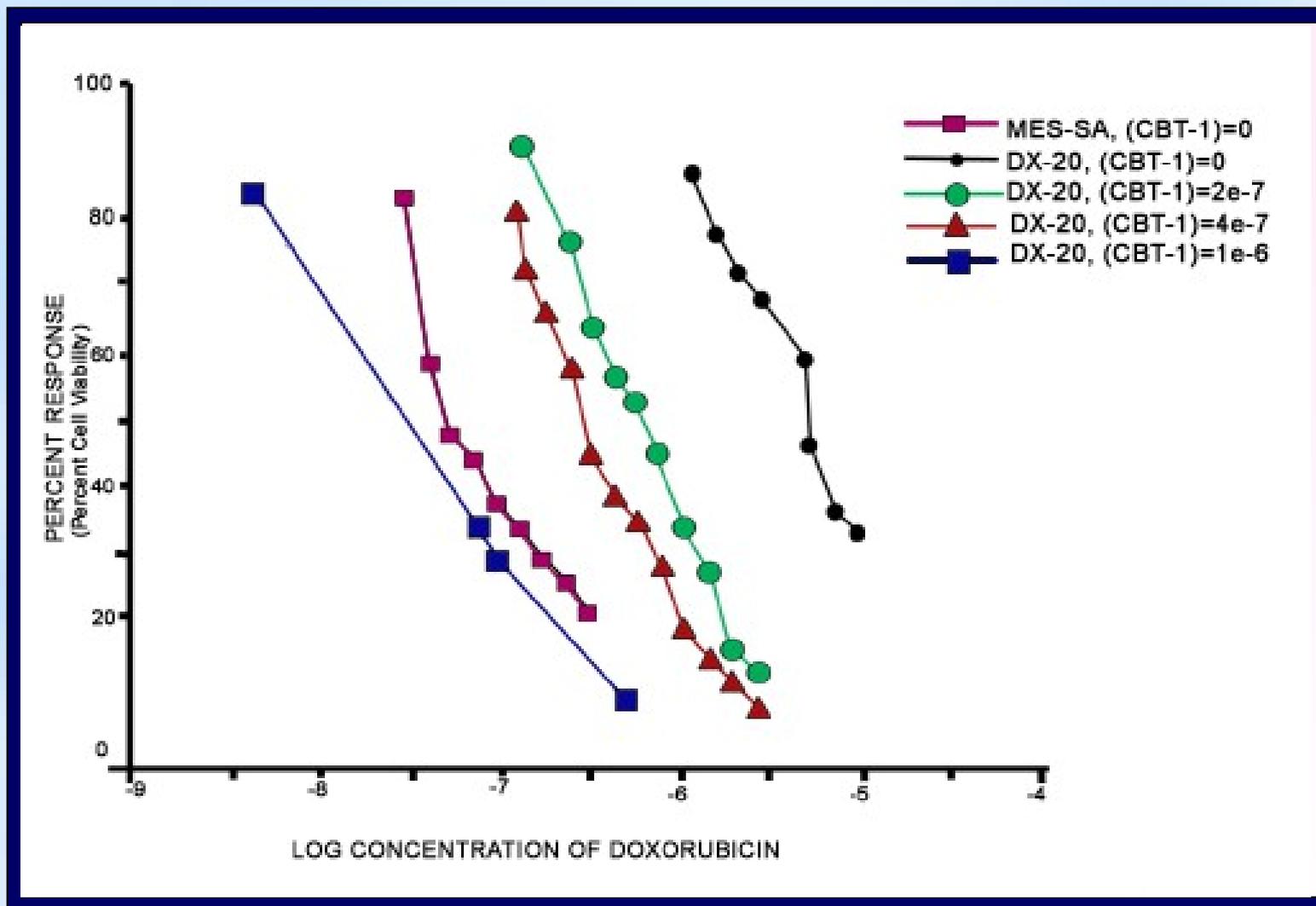
Depsipeptide

Taxol

^{99m}Tc-sestamibi

Carboplatin

In Vitro Analysis With Doxorubicin



Drug Development Status of CBT-1[®]

- **Phase I, II and III Clinical Trials have been completed, tabulated and summarized in the New Drug Application.**
- **New Drug Application (NDA) for CBT-1[®] to reverse multidrug resistance to chemotherapy in all types of refractory/relapsed cancers, is filed with the FDA and is currently being reviewed.**

CBT-1[®] Clinical Testing as MDR Modulator

Phase I

- **Phase I Trial of Concurrent CBT-1[®] and Doxorubicin for the Treatment of Cancer in Individuals Who have failed Prior Chemotherapy.**
- **Phase I/IIA Study of CBT-1[®] and Taxol[®] in Patients with Relapsed/Refractory Cancers.**
- **Phase I Feasibility Study of CBT-1[®] and Carboplatin/Taxol[®] in Patients with Unresectable NSCLC.**
- **Phase I Feasibility Study of CBT-1[®] and Adriamycin/Taxol[®] in Patients with Unresectable Breast Cancer.**

CBT-1[®] Clinical Testing as MDR Modulator

Phase II

- **Phase II study with high dose Cytosine Arabinoside and Daunorubicin in multiple relapsed or refractory AML.**
- **Phase II with Paclitaxel in various advanced relapsed cancers including GI, multiple myeloma, breast, SCLS, NSCLC, ovarian, prostate, cervical and head&neck.**
- **Phase II Pharmacodynamic study of CBT-1[®] and Paclitaxel evaluating PGP inhibition in tumor and normal tissue conducted in collaboration with the National Cancer Institute.**

Phase III

- **Phase III placebo controlled randomized study of CBT-1[®] and Carboplatin and Paclitaxel in NSCLC.**

CBT-1[®] Safety and Efficacy Profile

Preclinical and Clinical research has consistently demonstrated the potential for CBT-1[®] to be safe and effective.

The drug is safe, well tolerated, lacks harmful pharmacokinetic interactions when combined with chemotherapeutic agents, has specificity for P-gp and MDR-1, is stable, orally available, and has produced clinically objective responses in heavily pre-treated and/or late cancers.

Advantages of CBT-1[®]

- **Reverses drug resistance in multiple cancer types.**
- **Strong safety and tolerability profile: side effects are manageable and non-life threatening.**
- **In advanced relapsed cancers clinical trials demonstrate a meaningful response rate.**
- **Oral administration prior to chemotherapy achieves required concentration to reverse drug resistance.**
- **Does not alter the pharmacokinetic profile of Doxorubicin and Paclitaxel (two MDR substrates).**
- **Enhances most common chemotherapy agents in current oncology protocols.**

CBT-1[®] – USA Market Potential

- Excess of 6 million existing cancer patients.
- Approximately 1.5 million new cancer patients each year.
- Approximately 571,000 cancer deaths each year.
- Approximately 50% of all patients treated receive chemotherapy.
- As much as 97% of cancer deaths may be attributable to the presence of multidrug resistance.
- A 1% reduction in the USA cancer mortality rate could contribute as much as \$500 billion to the USA economy.

Patent Life

Up to 16 years with FDA approval

Special Status

- No drugs approved or in public pipeline that reverse multidrug resistance to chemotherapies in cancers
- CBT-1[®] potential “First in Class” and “Best in Class”
- CBT-1[®] will provide an “unmet medical need for a life threatening disease” – multidrug resistant cancers

Clinical Testing CBT-1[®] as MDR Modulator Currently Planned

Future phase III clinical trials that
have been prioritized:

- ✓ Sarcoma
- ✓ AML
- ✓ Breast
- ✓ Ovarian
- ✓ Colorectal
- ✓ Head and Neck
- ✓ Others

CBT-1[®] Partnering Status

Available for out-licensing

USA and Europe

Developer/Owner

**CBA Pharma, Inc.
670 Perimeter Drive
Lexington, Kentucky 40517
859-266-5757**

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Revised October 2012

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CBT-1[®] SAFETY PROFILE

Of the total number of adverse events (AE's) reported for patients treated with CBT-1[®], 33% were assessed as related to the drug. The most frequently occurring events associated with CBT-1[®] were:

- *Nausea 4.3%
- *Vomiting 2.8%
- *Diarrhea 2.8%
- *Neutropenia 2.2%
- *Leukopenia 1.9%
- *Low Hemoglobin 1.5%
- *Fatigue 1.4%

Company Info



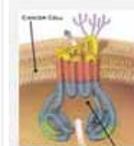
CBA Pharma, Inc. is organized to exclusively manufacture, market, license and distribute to the medical oncology community a drug, CBT-1[®], developed to be an effective treatment for cancer that has developed or may develop drug resistance to chemotherapy.

CBT - 1[®]

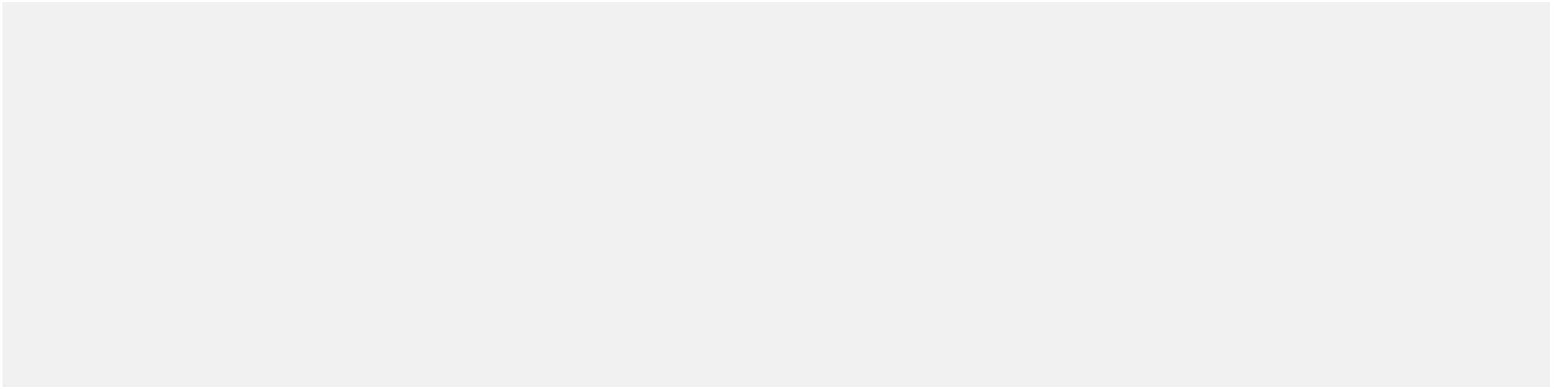


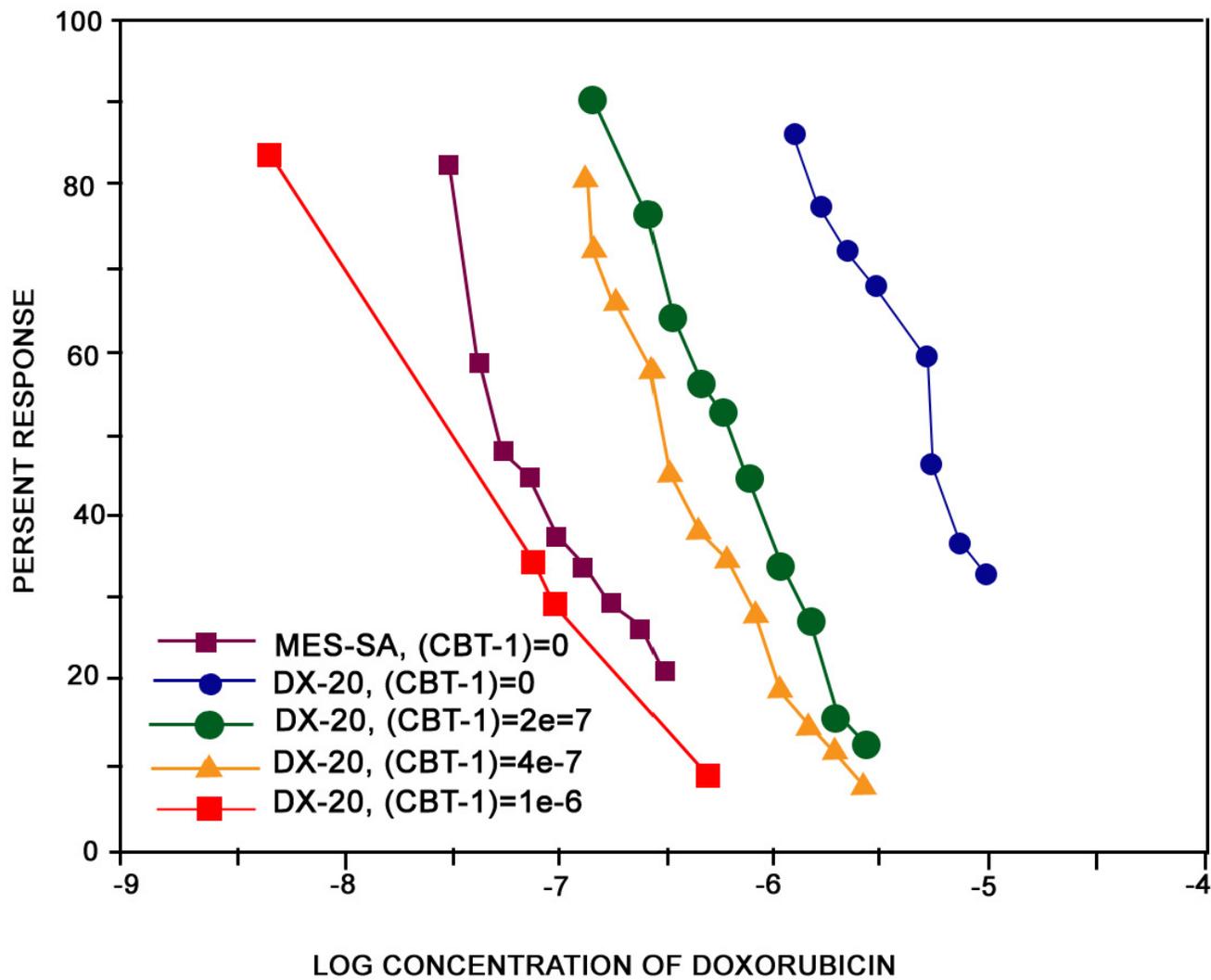
CBT-1[®], taken orally as a pill, was developed to reverse multi-drug resistance in cancer cells and to become part of a Cancer Treatment Program that is administered before a cancer cell can become drug resistant.

Multi-Drug Resistance



(MDR) is the phenomenon whereby cells become resistant to a variety of chemotherapy drugs. Resistance of cancer cells to chemotherapy remains the major cause of treatment failure.





32 pages withheld immediately after this page as copyright material

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