Project:
NanoInnovation Initiative
NANOTECHNOLOGY plan

Company: EBEWE-pharma

Presenter: Tamar Chachibaia, Tbilisi, Georgia

NANOTECHNOLOGY – advance in pharmaceutical industrial process

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Strategic Initiative

Nanotechnology - Implication in Oncology

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Nanotechnology will change the very foundations of cancer diagnosis, treatment, and prevention

- Novel nanodevices capable of one or more clinically important functions, including detecting cancer at its earliest stages, pinpointing its location within the body, delivering anticancer drugs specifically to malignant cells, and determining if these drugs are killing malignant cells.
- These nanodevices are evaluated in clinical trials, researchers envision that nanotechnology will serve as multifunctional tools that will not only be used with any number of diagnostic and therapeutic agents, but will change the very foundations cancer diagnosis, treatment, and prevention.

NANOTECHNOLOGY - BRIDGE TO THE FUTURE

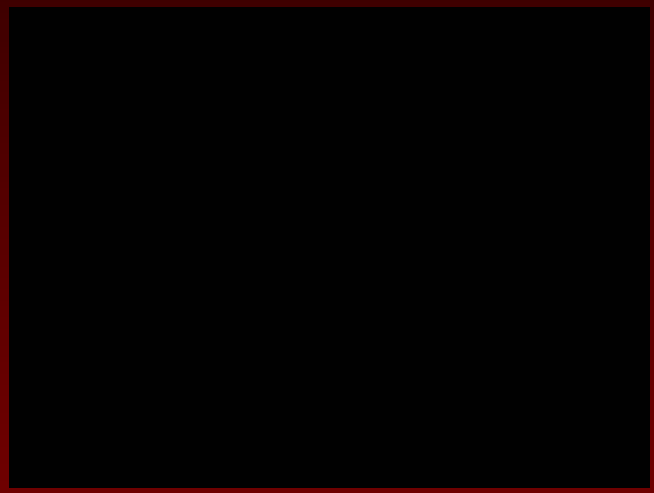
Apple recently introduced tiny iPod Nano music player

- 'Nano" is a term creeping into our vocabulary and our culture these days, and it's likely to be one of the buzzwords of the future, the way "cyber" was in the '90s.
- Nanotechnology is expected to produce an immense new wave of novel products and improved versions of what we have now. Nanotechnology is widely expected to be one of the most important industrial innovations of the 21st century. U.S. Sen. Ron Wyden, Democrat from Oregon, has said, "My own judgment is that the nanotechnology revolution has the potential to change the world on a scale equal to, if not greater than, the computer revolution.
- There should be major advances in medical technology

NANOTECHNOLOGY AND CANCER

By the year 2015 National Cancer Institute plan to meet the goal of eliminating death and suffering from cancer. The National Cancer Institute is engaged in efforts to harness the power of nanotechnology to radically change the way we diagnose, image, and treat cancer.

The NCI Alliance for Nanotechnology in Cancer represents an investment of $144.3 million over five years.



Nanotechnology is Here

- Nanoscale drug delivery devices are being developed to deliver anticancer therapeutics specifically to tumors. Liposomes are one such "first generation" nanoscale device. Liposomal doxorubicin is used to treat specific forms of cancer, while liposomal amphotericin B treats fungal infections often associated with aggressive anticancer treatment. Recently, a nanoparticulate formulation of the well-known anticancer compound taxol was submitted as a new treatment for advanced stage breast cancer.

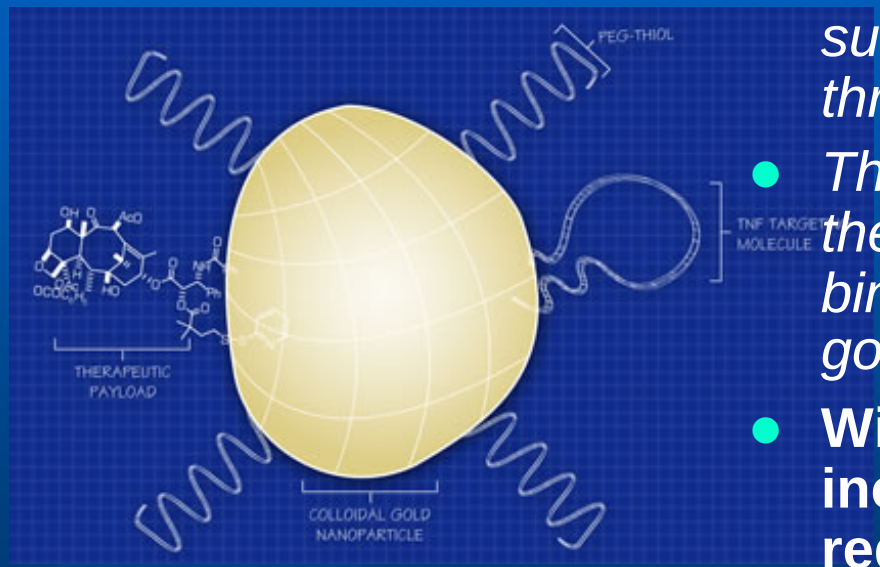
ABRAXANE™ (Paclitaxel) was approved in February 2005 by the FDA.

- **ABRAXANE™ - for Injectable Suspension is the first and only approved taxane for the treatment of metastatic breast cancer in a new class of albumin-bound nanotechnology that is free of solvents.**
- **As a solvent-free chemotherapy agent, ABRAXANE increases the convenience of administration.**
- **For the first time, the anticancer drug paclitaxel can now be delivered using the protein albumin rather than a chemical solvent.**

Abraxane™ is trademark of BioScience, Inc.(USA)

- American Pharmaceutical Partners have announced that its cancer-fighting drug Abraxane (consisting of 130-nanometer spheres of protein and paclitaxel) has demonstrated greater tumour reduction and fewer side effects when compared to a solvent-dissolved equivalent.
- ABRAXANE ™ for Injectable Suspension launched by Abraxis Oncology, the proprietary drug division of (APP) American Pharmaceutical Partners, Inc.

CytImmune - PEGilated gold nanoparticals - A Novel Vector for Tumor Directed Drug Delivery



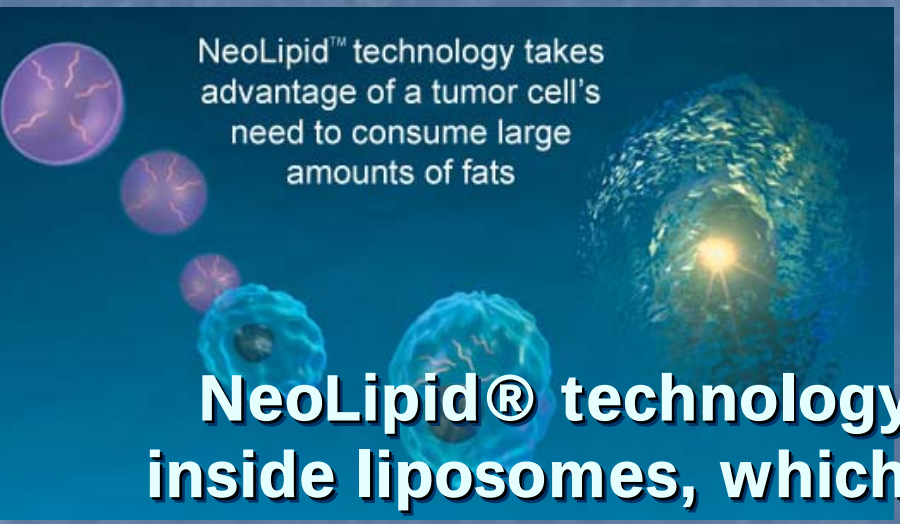
- *In 2000, CytImmune discovered that pegylated colloidal gold nanoparticles bind anti-cancer therapeutics on their surface and carry these drugs safely through the blood stream.*
- *Thiolated forms of small molecule therapeutics, such as paclitaxel, TNF, bind directly to the surface of colloidal gold nanoparticles.*
- **With tumor targeting resulting in increased drug levels in the tumor and reduced drug uptake by healthy organs, the technology improves efficacy and reduces toxicity.**

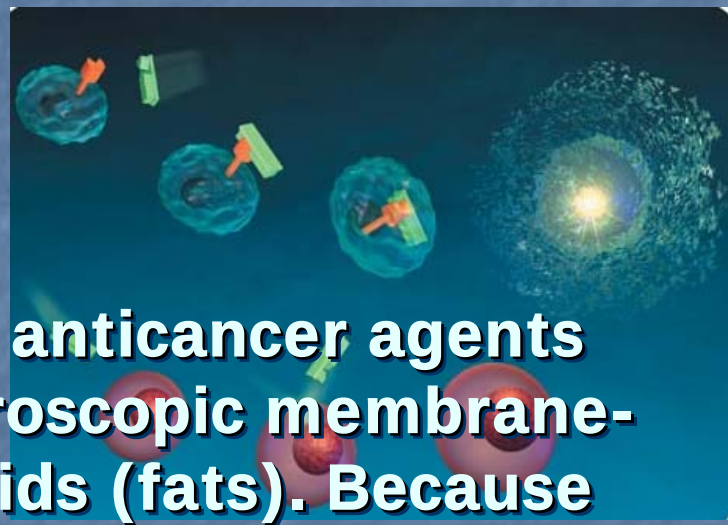
An example of industry-government partnerships in this area is the project "Using nanosized particles for more effective cancer therapy" (National Institute of S&T, National Institutes of Health, National Cancer Institute, CytImmune Sciences Inc., and EntreMed, Inc.).

How works Colloidal Gold?

- Polyethylene glycol (PEG) masks particles from immune recognition preventing uptake by liver and spleen
- Nanoparticles exit circulatory system only at the tumor neovasculature due to leakiness of blood vessels
- Particles too large to exit circulation elsewhere
- TNF targeting molecule on particle's surface binds to receptors causing rapid absorption of drug in and around tumor.

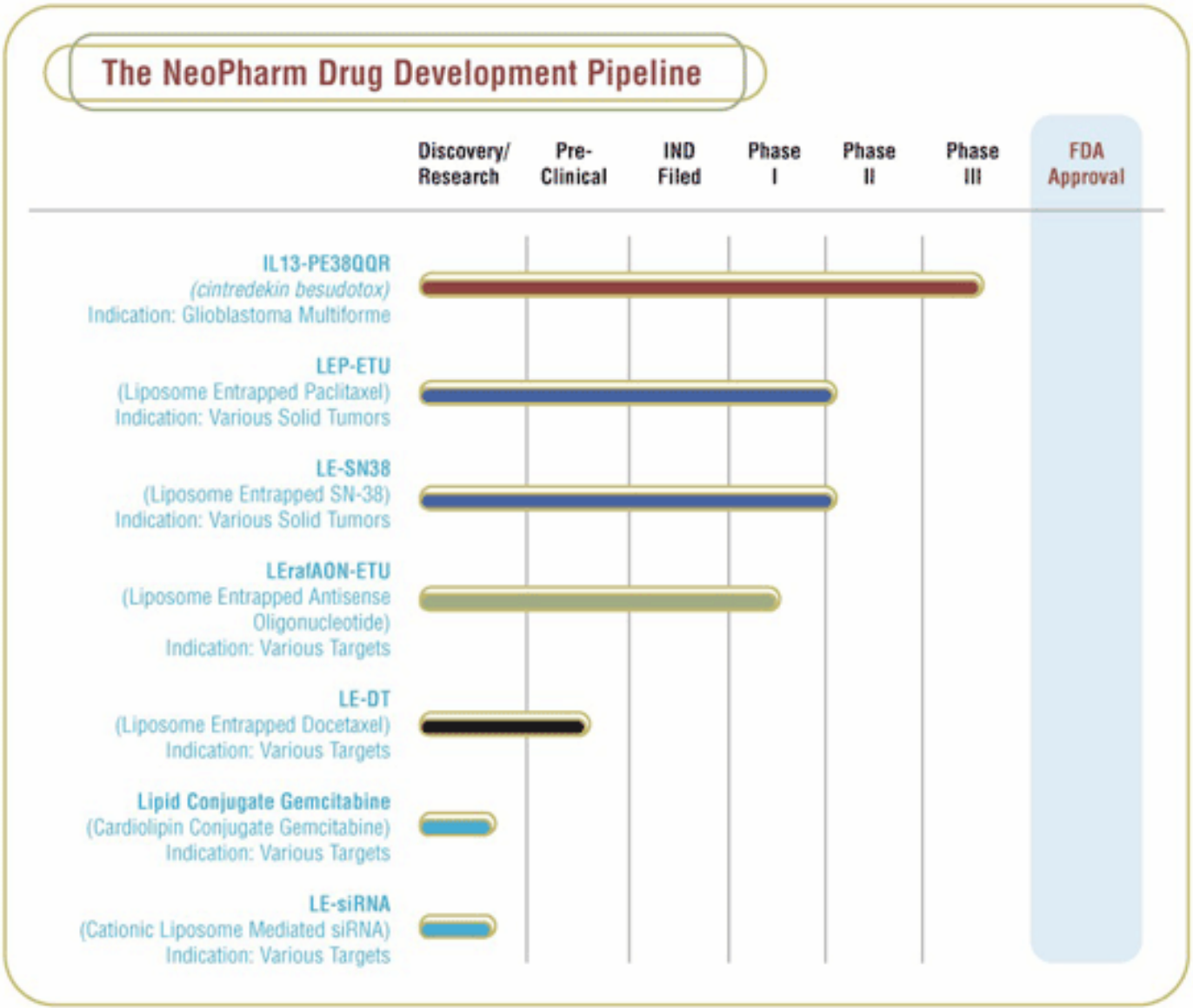
NeoPharm is a biopharmaceutical company dedicated to the research, discovery, and commercialization of new and innovative cancer drugs for therapeutic applications. NeoPharm has built its drug portfolio based on its two novel proprietary technology platforms: a tumor-targeting platform and the NeoLipid® drug delivery system.





NeoLipid® technology entraps anticancer agents inside liposomes, which are microscopic membrane-like structures created from lipids (fats). Because tumor cells need to consume large amounts of fats to sustain their rapid growth, they eat the liposome, while at the same time absorbing the anticancer agents.

NeoLipid® DRUG DELIVERY PLATFORM



ACUSPHERE Inc. is a specialty pharmaceutical company that develops new drugs and improved formulations of existing drugs using its proprietary porous microparticle technology.

AI-850, our initial product candidate utilizing our HDDS technology, is a readily dissolving formulation of the hydrophobic drug, paclitaxel, the active ingredient in the cancer drug, Taxol. To dissolve paclitaxel, Taxol contains Cremophor, which is believed to cause severe hypersensitivity reactions, such as an extreme allergic reaction called anaphylaxis. Therefore, Taxol is typically administered using pre-medications and by long infusions to patients with cancer. By putting nanoparticles of paclitaxel into sponge-like microparticles, is created a paclitaxel formulation that is free of Cremophor and consists of paclitaxel nanoparticles in a porous, hydrophilic matrix, composed primarily of a sugar that has been proven to be innocuous in other injectable drugs.

BioDelivery Sciences International, Inc.

Drug	Indication	Status
Emezine	Nausea/Vomiting	Partnered
BEMA Fentanyl	Breakthrough pain	Proprietary
Bioral Amphotericin B	Fungal infections	Proprietary
Bioral NSAID	Pain	Licensed
Bioral paclitaxel	Oncology	Avail. for Licensing
Bionasal Amphotericin B	Chronic rhinosinusitis	Partnered
Biorazyme	Gauchers Disease	Avail. for Licensing
Bioral siRNA	Infectious disease/cancer	Avail. For Licensing

Aphios Corporation is developing enhanced therapeutics for health maintenance and the treatment of human diseases with a focus on infectious diseases, cancer and quality-of-life medicines

- Aphios has utilized its patented *SuperFluids™CFN* technology to form nanosomes (small, uniform liposomes) of paclitaxel. Liposomes are microscopic vesicles of phospholipid bilayers comprised of single or multiple lipid bilayers. Most liposomes are non-toxic, non-antigenic and biodegradable in character since they have the molecular characteristics of mammalian cell membranes. Hydrophobic compounds are trapped inside the lipid bilayers, masking the toxic nature paclitaxel and permitting a biocompatible formulation to be administered.

TaxosomesTM

- Aphios has developed and patented a nanosomal formulation of Paclitaxel, *Taxosomes.*™ The formulation is Cremophor-free and produced by Aphios' patented phospholipid nanosomes technology [U.S. and European Patents, 1995, 1997, 1998 and 2002]. Harvard Medical School researchers have demonstrated that *Taxosomes*™ is much less toxic *in vitro* than Taxol,® while being twice as effective in the in vivo treatment of nude mice with breast cancer xenografts.

NanoMed Pharmaceuticals, Inc.

- **NanoMed has developed a scaleable nanoparticle manufacturing technology (Nanotemplate Engineering) to deliver small molecules, peptides, proteins, plasmid DNA, and diagnostic agents.**
- **The company is utilizing this novel platform technology to develop new and improved formulations for two approved chemotherapeutic drugs -- paclitaxel (Paclitaxel NP™) and doxorubicin (Doxorubicin NP™) -- and a new indication for a third approved therapeutic agent for use as a novel anti-cancer drug (NAC NP). The therapeutic focus is breast, lung, and colorectal cancer.**

SONUS pharmaceuticals

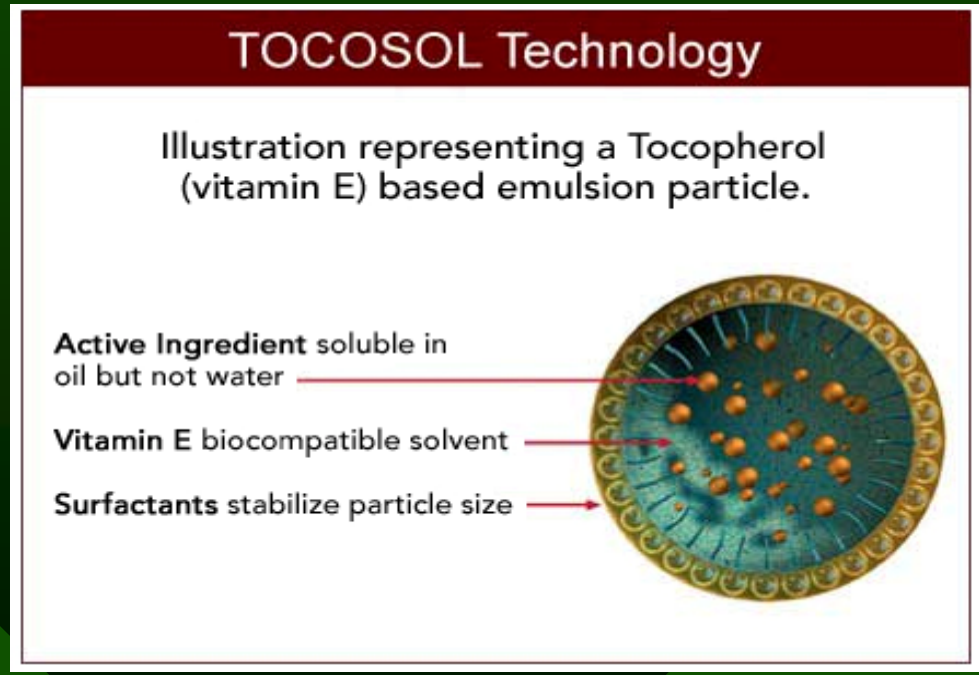
- **The Company's lead product candidate is TOCOSOL® Paclitaxel, an injectable, ready-to-use formulation of the widely prescribed anti-cancer drug paclitaxel.**
- **The product is administered to patients in a short 15-minute infusion compared to the prolonged three-hour infusion required with Taxol. TOCOSOL Paclitaxel has been designed to overcome the limitations associated with Taxol® and generic paclitaxel-based chemotherapy, including time consuming and expensive preparation of the products prior to administration, long infusion times and undesirable or treatment-limiting side effects.**
- **Sonus has completed patient enrollment in Phase 2a studies of TOCOSOL Paclitaxel in non-small cell lung, bladder and ovarian cancers, and Phase 2b studies are ongoing in bladder and breast cancers. In addition, the U.S. Food and Drug Administration has completed a Special Protocol Assessment (SPA) for the pivotal Phase 3 trial of TOCOSOL Paclitaxel, which Sonus expects to initiate in 2005.**

SONUS pharmaceuticals

- The TOCOSOL® technology uses vitamin E and vitamin E derivatives to solubilize, stabilize and formulate drugs with the goal of enhancing their delivery, safety and efficacy. The Company's development strategy is:

- Develop proprietary formulations of therapeutic drugs utilizing the TOCOSOL technology platform; and

- Identify and acquire additional therapies and technologies in oncology and related fields in order to expand product pipeline and corporate capabilities.

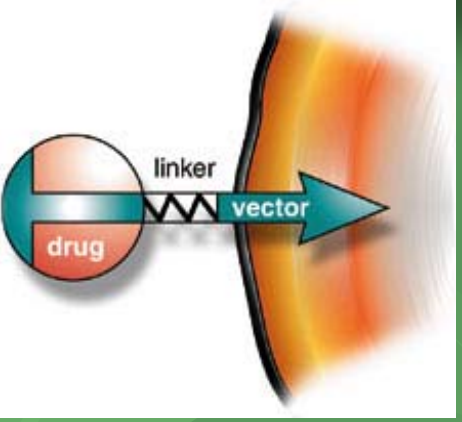


Synt:em announces its acquisition by Sonus Pharmaceuticals

About Synt:em

Synt:em S.A. is an emerging drug discovery company developing novel drugs using its proprietary drug design technologies to discover and develop drug transport conjugates. Company employs its technology platform to design short peptide vectors, known as Pep:trans vectors.

Pep:trans™ peptide-derived vectors transport drugs across biological membranes and bring them directly to their site of pharmacological action.
Drugs linked to Pep:trans™ typically have shown up to 100-fold enhancement in brain uptake resulting in an associated improvement of pharmacological activity in animal models.



Synt:em has developed short peptide vectors, termed SynB vectors, that are able to cross cellular membranes. In an effort to address the problem of MDR in cancer chemotherapy, scientists at Synt:em coupled the anticancer agent doxorubicin with various SynB vectors and tested their *in vitro* cytotoxicity in human erythroleukemic (K562/ADR) resistant cells. The conjugate showed potent dose-dependent inhibition of cell growth against K562/ADR cells as compared to treatment with doxorubicin alone. Doxorubicin exhibited IC50 concentrations that were 20 times higher than vectorized doxorubicin.

Synt:em announces its acquisition by Sonus Pharmaceuticals

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ALZA Corporation's STEALTH® liposomal technology

- ALZA Corporation's STEALTH® liposomal technology, developed for state-of-the-art intravenous drug delivery, is the basis for the anticancer agent Doxil® (doxorubicin HCl liposome injection).
- ALZA is now applying this technology to the delivery of other cancer therapeutics and gene therapy vectors.
- The proprietary STEALTH® liposomes evade recognition by the immune system because of their unique polyethylene glycol (PEG) coating.

Advectus Life Sciences, Inc.

Advectus Life Sciences Inc. holds the exclusive worldwide rights including patents to this nanoparticle-based technology for the delivery of approved cancer fighting drugs across the blood-brain barrier for the treatment of brain tumors. Preliminary tests have shown that this technology may have the potential to overcome major obstacles in treating brain cancer.

P80DOX-NP is a novel delivery method for Doxorubicin that crosses the blood-brain barrier. This series of pre-clinical studies will test the responsiveness of tumors in the brain to this compound. Successful demonstration of an antitumor effect could serve as a basis for a clinical trial using P80DOX-NP to treat the large group of patients with brain metastases. The study is designed to lead into Phase I Clinical Trials.

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Spherics, Inc

Schedule and Dose Adjustments for Improved Bioavailability of an Oral Repeat-dose Paclitaxel Nanoparticle Formulation

(Feasibility study - 2004)

Paclitaxel exists in several states, e.g., semicrystalline, dehydrate and amorphous and is generally supplied in the semi-crystalline state. A micronization method that could reduce particle size and reduce crystallinity of paclitaxel would increase absorption of both particulate and soluble drug.

The paclitaxel nanoparticle formulations in the present study were prepared using a proprietary phase-inversion precipitation technique, to produce discrete particles of amorphous paclitaxel in the size range of 300 nm. The oral pharmacokinetics of the PNF were evaluated after single and repeat dosing in fasted mice. Paclitaxel nanoparticles were fabricated via a phase inversion technique.

Spherics, Inc /701 George Washington Highway / Lincoln, RI 02865 /
Tel: (401) 334-7800 Fax: (401) 334-9180 Email: info@spherics.com

•Presented at the 2005 Annual Meeting (Cincinnati, OH)

1.Fabrication of micro and nanoparticles of paclitaxel-loaded Poly L Lactide for controlled release using supercritical antisolvent method: Effects of Thermodynamics and Hydrodynamics

2. Paclitaxel-loaded Biodegradable Nanoparticles Developed by Dialysis and ElectroHydrodynamic Atomization Methods

3.Micro- and Nano-Particles Developed by Electrohydrodynamic Atomization for the Sustained Delivery of Paclitaxel to Treat C6 Glioma

4. In vitro study of anticancer drug doxorubicin in PLGA-based microparticles

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Implantable 5-FU-Microspheres

Implantierbare 5-FU-Bio-Mikrosphären

Philippe Menei, M.D., Ph.D., Neurochirurg an der Universitätsklinik Angers in Frankreich, versucht, Gliome Lokal zu bekämpfen, indem er in eine Trägersubstanz ein radiosensibilisierendes Chemotherapeutikum einbettet, das dann am Tumor über einen längeren Zeitraum freigesetzt wird.

Philippe Menei, M.D., Ph.D.
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Drug Delivery Leader - Nektar Therapeutics

- Nektar is a leader in three broadly applicable technology platforms: Molecule Engineering, Particle Engineering, and Delivery Solutions for oral, injectable, and pulmonary administration. We have partner collaborations with more than 25 pharmaceutical and biotechnology companies, including Pfizer, Roche, Amgen, Bristol-Myers Squibb, Scherig-Plough, UCB Pharma, Chiron, InterMune, Serono. This technologies are essential to six drugs approved in the United States and/or Europe.
- The combination of technology leadership and development expertise allows Netar to capitalize on the rapidly expanding market for drug delivery solutions, which is estimated to grow from $50 billion in 2000 to more than $100 billion by 2005.

Nektar Advanced PEGylation

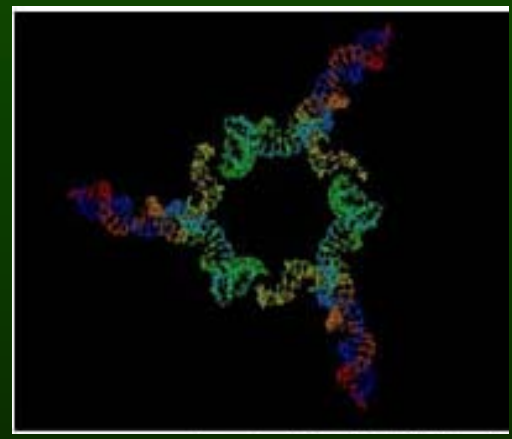
Nectar Therapeutics September 8 , 2005, San Carlos, California

- **Nektar Reports that FDA Advisory Committee Recommends Approval of Exubera® for Use in Adults with Type 1 and Type 2 Diabetes**
- Nektar Therapeutics (Nasdaq:NKTR) today reported that Pfizer Inc and the sanofi-aventis Group said that a U.S. Food and Drug Administration (FDA) advisory committee panel has recommended the approval of Exubera® (insulin [rDNA origin] powder for oral inhalation), an inhaleable, rapid-acting, dry powder insulin for the treatment of adults with type 1 and type 2 diabetes.

Amgen	Neulasta™ (pegfilgrastim) Neutropenia	FDA Approved
Bristol-Myers Squibb	Definity® Vial for (Perflutren Lipid Microsphere) Injectable Suspension (PEG) Hepatitis C	FDA Approved
Eyetech	Macugen™ (pegaptanib sodium) Hepatitis C	FDA Approved Filed in Europe
Pfizer	Somavert® (pegvisomant) Acromegaly	FDA Approved Approved Europe
Pfizer	Exubera® (inhaled human insulin powder)	Filed with FDA Filed in Europe
Roche	PEGASYS® (peginterferon alfa-2a)	FDA Approved Marketed Europe
Schering-Plough	PEG-INTRON® (peginterferon alfa-2b)	FDA Approved

UCB Pharma	Cimzia™ (PEG-anti-TNF alpha antibody fragment)	Phase III
Roche	CERA (Continuous Erythropoiesis Receptor Activator)	Phase III
Chiron	Tobramycin Inhaled Powder (TIP)™	Phase III
Confluent Surgical	SprayGel™ Adhesion Barrier System (PEG-hydrogel)	Phase II/III U.S. Marketed Europe
Solvay Pharmaceuticals	Inhaled Dronabinol	Phase II
Undisclosed	Undisclosed (PEG)	Phase II
UCB Pharma	CDP 791	Phase I
InterMune	PEG-Infergen (PEG-interferon alfacon-1)	Phase I*
Pfizer	PEGylated undisclosed	Phase I
Proprietary Product	Inhaled Amphotericin B	Phase I
Proprietary Product	Inhaled ICU Antibiotics	Phase I (proof of concept)
Serono	PEG-interferon beta 1a	Phase I*

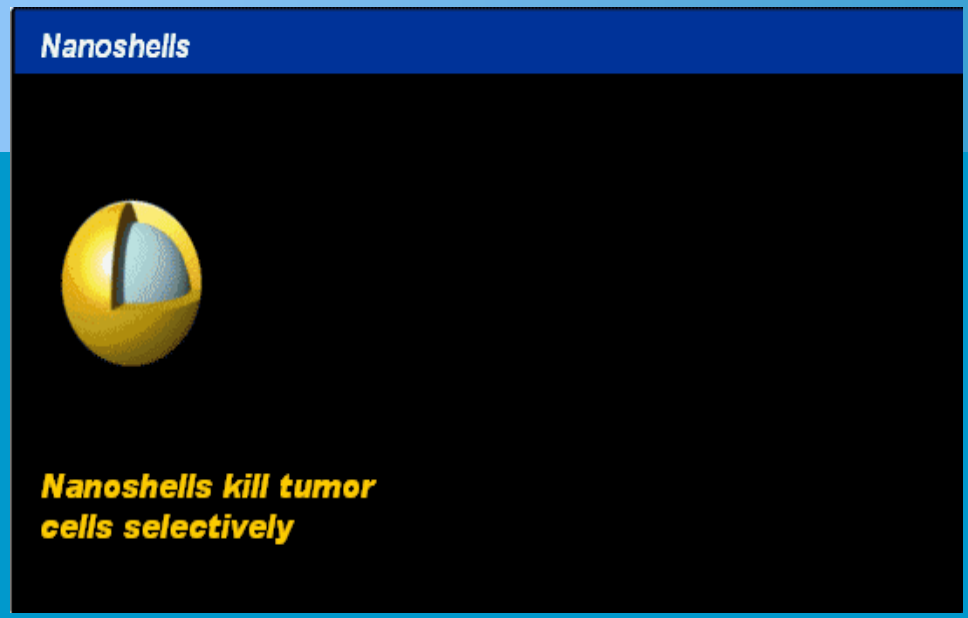
Purdue Scientists Treat Cancer with RNA Nanotechnology



- The researchers developed some of their RNA-manipulation techniques in 2003 by building an RNA nanomotor.

  (Controllable Self-Assembly of Nanoparticles for Specific Delivery of Multiple Therapeutic Molecules to Cancer Cells Using RNA Nanotechnology, Nano Letters, September 14, 2005)

- Using strands of genetic material, Purdue University scientists have constructed tiny delivery vehicles that can carry anticancer therapeutic agents directly to infected cells, offering a potential wealth of new treatments for chronic diseases



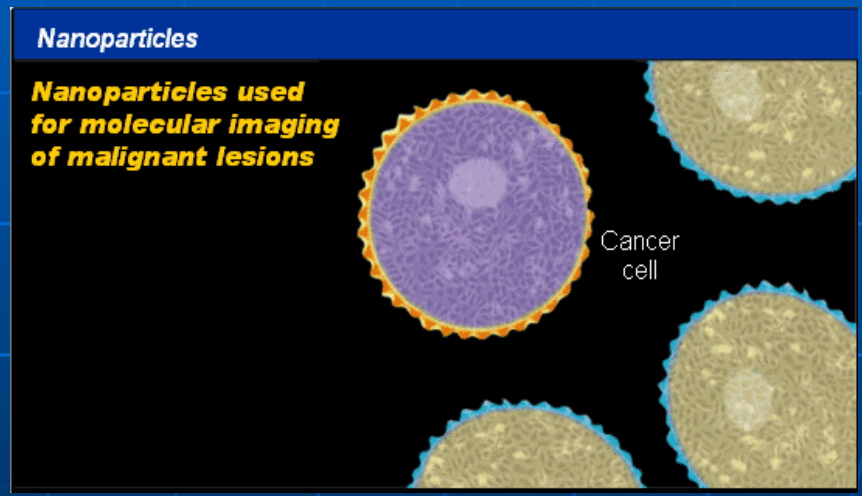
Nanoshells have a core of silica and a metallic outer layer. Nanoshells will preferentially concentrate in cancer lesion sites.

As shown in this example, scientists can then externally supply energy to these cells. The specific properties associated with nanoshells allow for the absorption of this directed energy, creating an intense heat that selectively kills the tumor cells. The external energy can be mechanical, radio frequency, optical - the therapeutic action is the same.

The result is greater efficacy of the therapeutic treatment and a significantly reduced set of side effects.

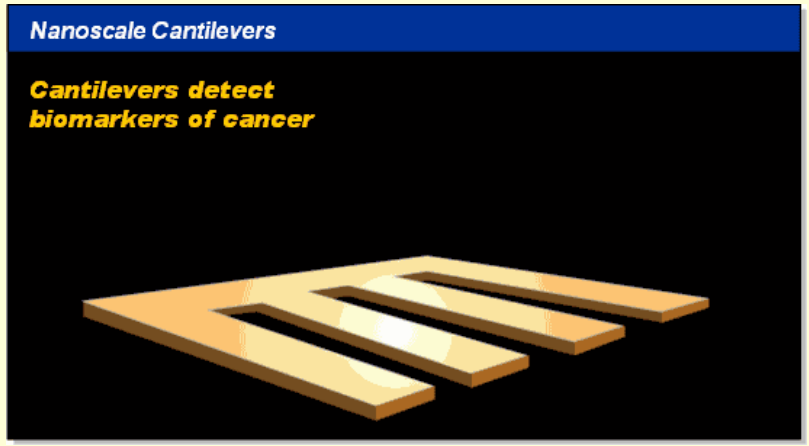
Nanoparticles

- Nanoscale devices have the potential to radically change cancer therapy and dramatically increase the number of highly effective therapeutic agents.
- In this example, nanoparticles are targeted to cancer cells for use in the molecular imaging of a malignant lesion. Large numbers of nanoparticles are safely injected into the body and preferentially bind to the cancer cell, defining the anatomical contour of the lesion and making it visible.
- These nanoparticles give us the ability to see cells and molecules that we otherwise cannot detect through conventional imaging.



Cantilevers

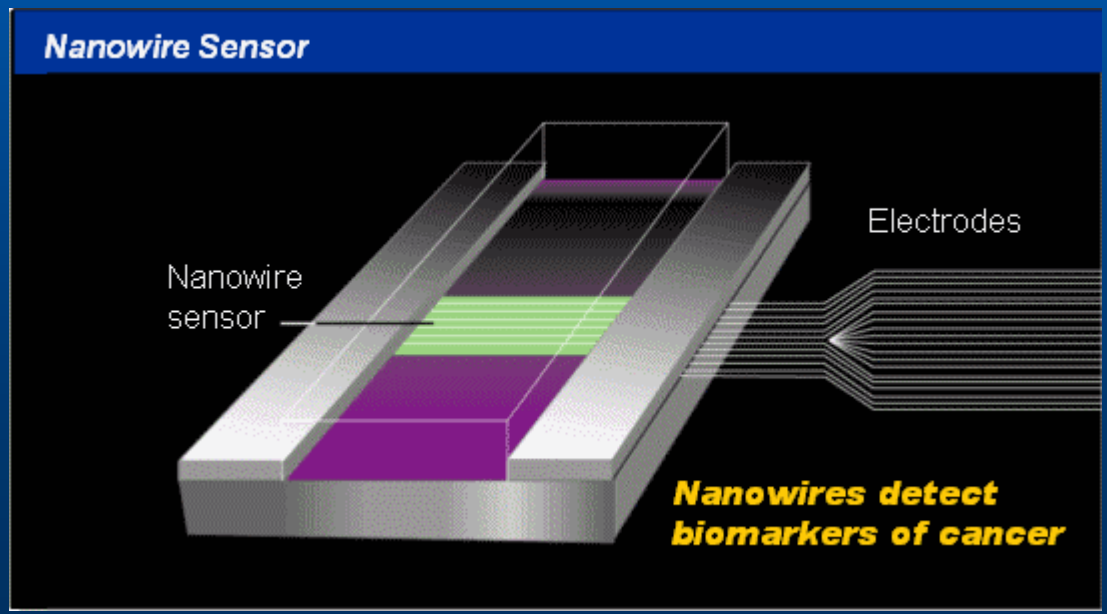
Nanoscale cantilevers - microscopic, flexible beams resembling a row of diving boards - are built using semiconductor lithographic techniques. These can be coated with molecules capable of binding specific substrates-DNA complementary to a specific gene sequence, Nanoscale cantilevers, constructed as part of a larger diagnostic device, can provide rapid and sensitive detection of cancer-related molecules.



Nanowires

In this diagram, nano sized sensing wires are laid down across a microfluidic channel. As particles flow through the microfluidic channel, the nanowire sensors pick up the molecular signatures of these particles and can immediately relay this information through a connection of electrodes to the outside world.

They can detect the presence of altered genes associated with cancer and may help researchers pinpoint the exact location of those changes.



Nanoparticle Drug Delivery
Technology, Therapies, and Prospects. February 2005
Greystone Associates

- At present, there are 30 main drug delivery products on the market. The total annual income for all of these is approximately US$33 billion with an annual growth of 15% (based on global product revenue).
- Advances in nanotechnology are creating a host of opportunities for drug developers.
- The number of research programs and active drug development projects has escalated as funding to nanotechnology developers has increased
- A variety of nanostructures are being investigated as functional drug carriers for a wide range of therapies
- The capabilities that evolving technologies possess will leads to a dramatic increase in the number of therapies delivered via nanoparticles
- Nanoparticles can improve therapeutic outcomes because drugs can be delivered directly to the tissue and in controlled doses related to the patient's personal requiremen.

Greystone Associates
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February 2005

Greystone Associates

is a medical technology consulting firm. Forecasts and projections cover the period from 2004 to 2008.

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NANOTECHNOLOGY FUTURE INSIGHTS

- The US National Science Foundation (NSF) expects nanotechnology to account for around half of all pharmaceutical industry sales by 2010.
- As part of NCI mission to accelerate the application of nanotechnology to the major challenges in clinical oncology and basic cancer research, the NCI Alliance for Nanotechnology in Cancer is dedicating $144.3 million as part of a 5 year initiative for nanotechnology in cancer research.
- Nektar developed more than 50 products with partners . . . 19 approved, filed, or in human clinical trials, including 6 approved in the U.S. or Europe.

Near-term Nanoparticle Delivery Therapeutics

- Autoimmune Diseases
- Cardiovascular Medicine
- Cancer Therapy
- Musculoskeletal
- Vaccines
- Emerging Markets
- Existing/Approved Drugs
- New Drug Discovery
- DNA-based Therapies

Nanoparticle Delivery Technology Platforms

- CAP (BioSante)
- Cyclosert (Insert Therapeutics)
- Emulsiphan (Cornerstone)
- Hydroplex (ImaRx)
- LiPlasomes (LiPlasome Pharma)
- Medusa (Flamel)
- Micellular Nanoparticles (Novavax)
- NanoBiodrugs (Nanobiotix)
- Nanocrystal (Elan)
- NanoCure (Advectus)
- Nanoparticle Aggregate Technology (Access)
- Nanosomes (Molecular Therapeutics)
- Smarticles (Novosom)
- TargeTran (Intradigm)
- TransDrug (BioAlliance)
- VivaGel (Starpharma)

Nanoparticle Drug Delivery – Company Profiles

- Access Pharmaceuticals
- Acusphere
- Advectus Life Sciences
- American Pharmaceutical Partners
- Aphios
- BioAlliance
- BioDelivery Sciences International
- Biophan Technologies
- BioSante Pharmaceuticals
- Capsulution Nanoscience AG
- Cornerstone Pharmaceuticals
- Dendritic Nanotechnologies
- Elan
- Flamel Technologies
- ImaRx Therapeutics
- Insert Therapeutics
- Intradigm
- ISTN
- Labopharm
- LiPlasome Pharma AS
- Medac GmbH
- Molecular Therapeutics
- NanoBioMagnetics
- Nanobiotix
- NanoCarrier
- NanoCure
- NanoCyte
- NanoMed Pharmaceuticals
- Nanospectra Biosciences
- Novavax
- Novosom AG
- Roche
- SoluBest Technology
- Starpharma Holdings
- Transgenex Therapeutics

NANOTECHNOLOGY - A POWERFUL RESEARCH ENABLER

- Nanotechnology is providing a critical bridge between the physical sciences and engineering, on the one hand, and modern molecular biology on the other. Materials scientists are learning the principles of the nanoscale world by studying the behavior of biomolecules and biomolecular assemblies.
- In return, engineers are creating a host of nanoscale tools that are required to develop the systems biology models of malignancy needed to better diagnose, treat, and ultimately prevent cancer.

NANOTECHNOLOGY - BRIDGE TO THE FUTURE

Apple recently introduced tiny iPod Nano music player

- Nanotechnology is the science of building devices at the molecular and atomic level. For example, a single data bit might be represented by only one atom some time in the future.
- Beyond being used in computers and communications devices, nanotechnology could be used extensively in biotechnology to build devices, fight disease, and change the properties of materials.
- NCI Legislative Update for National Cancer Advisory Board Congressional Activities
- Final Report for the 108th Congress, 2004