ACGT®

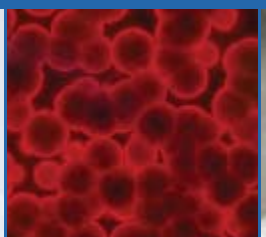
ALLIANCE FOR CANCER GENE THERAPY

National grants for cancer research

ANNUAL REPORT 2006

PROGRESS & PROMISE








2001 FIVE YEARS OF PROGRESS

Our Mission

ACGT is committed to building alliances between philanthropic individuals and organizations, and medical and academic institutions, to promote gene therapy research to combat cancer.

To this end, ACGT will identify, fund and monitor innovative research that meets a rigorous set of scientific standards and has the potential, in the foreseeable future, to treat cancers of all types.

Through this endeavor, ACGT will educate the public about the potential for cancer gene therapy and facilitate greater collaboration among the scientific community to foster the best possible research and ultimately the best treatment.

Alliance for Cancer Gene Therapy, Inc. (ACGT) is a 501(c)(3) non-profit public charity founded in 2001 by Barbara and Edward Netter to facilitate funding for high-potential research into gene therapy, in the hopes of realizing an effective alternative to the treatment and management of cancer.

TOWARDS THE PROMISE OF CANCER GENE THERAPY

ACGT is the only public charity in the nation dedicated exclusively to investing in research to promote cancer gene therapies.

Why gene therapy? Thanks to the advances of molecular medicine and the mapping of the human genome, we know now for certain that cancer is the result of defective or missing genes. Traditional treatments – surgery, chemotherapy and radiation – do much to ameliorate and sometimes destroy cancer cells, but do not repair the genetic make-up of cancerous genes to prevent recurrence or metastasis. This is the promise of gene therapy.

We expect in our lifetimes to see the realization of therapies that augment or replace current treatments, without the toxic affect to the body that cancer victims are forced to endure.

Among these gene therapies are:

- Gene proteins delivered directly to the tumor to facilitate cancer cell death.
- Medications that boost the immune system to recognize and destroy cancer cells, known as immunotherapy.
- Chemical agents that strangulate cancer cells by cutting off their blood supply, known as anti-angiogenesis, a technique with application to many diseases.
- Vaccines that will ultimately prevent cancer.

The long-term goal is to refine these techniques to make cancer a manageable disease, and someday eradicate the disease entirely. In the near future, we hope to move the many research projects currently underway towards clinical translations and medical practice.

Great progress has been made. This year alone, the NIH announced a successful gene therapy trial for melanoma, clinical trials for lung, head and neck cancers have yielded promising results, and there has been greater interest in gene therapy by biotech and pharmaceutical companies, which have begun to recognize their potential.

Progress takes time – not only time for research projects to bear fruit, but for our scientific community to provide the necessary oversight to ensure the integrity of results.

And progress requires funding. To-date, ACGT has funded 27 research projects representing 21 prestigious medical institutions, amounting to over $15 million in grant awards.

More is needed to accelerate progress. Moving forward, ACGT has committed one-half of our funding to research approaching clinical translation, and another half to discovery, a balance that will hopefully accelerate progress while ensuring innovation for the future.

- The Fund for Advancement awards up to $1 million to Investigators to stimulate the progression towards human trials and medical practice.
- The Fund for Discovery awards up to $500,000 to Young Investigators [tenure track assistant professors] seeking new methodologies. In this way, we encourage young talent to maintain a commitment to research and keep the pipeline flowing with possibilities.

Our unique alliance of medical professionals, business individuals and organizations, and philanthropists, has realized in five short years even greater progress than we might have expected. Going forward, we recommit our efforts towards the promise of gene therapy as the hope for cancer patients throughout the world.

Margaret C. Cianci, Executive Director

FIVE YEARS
27 RESEARCH PROJECTS

Message from our Founders



Progress in research cannot be measured in the same way we might traditionally define a progression – medical research is different from the path towards a space voyage or the building of a bridge. It is less a continuum and more of a matrix, filled with interconnected concepts and people, each on their own path towards the same end.

Medical progress seems less concrete for the very reason it is so important, and that is that research is about revealing the unknown. What matters most is that we keep at the forefront the creativity of thinking, tenacity and perseverance that makes progress possible.

The discovery and perfection of new treatments for cancer have been our target since the founding of the Alliance for Cancer Gene Therapy in 2001. We have never wavered from our belief that gene therapy will become the new medical paradigm for treating and someday eradicating cancer. The promise is even more credible to us now, as research continues to successfully transition from laboratory investigation to clinical translations.

The American Cancer Society announced this year that gains have been realized in recent years because of early detection. We are gratified that detection techniques have made it possible for cancer patients to be treated sooner, often more effectively, and that the lives of those struck by this awful disease can be extended. However, early detection is only one part of the equation. If we are to realize real gains in the war against cancer, new forms of treatment are crucial, and some of the best scientists and research centers in the country, and around the world, are now fully committed to cancer gene therapy as the best possible option.

In just five years, we have awarded grants to fund research into eight forms of deadly cancers, as well as research into medical approaches that have application to several forms of cancer. We have received positive feedback from three of the first completed research projects, which have paved the way to the next level of research. We have supported seven clinical translations that will move molecular medicine from the laboratory towards medical practice. We have facilitated important dialogue with the best minds in the field and cultivated greater communications between investigators around the country. We have happily seen the National Cancer Institute report a successful cancer gene therapy trial for melanoma, which will hopefully reinvigorate its commitment to funding future trials. We have engendered support from a broader array of donors and organizations. And we have committed ourselves to devoting more of our grant awards to clinical translation, in the hopes of encouraging investigators to move forward more rapidly.

Do we have a cure yet? No. But great progress has been made, and we have firmly positioned this organization to continue to be the driving force for progress in the future. We are more than optimistic; we are confident that cancer gene therapies are moving towards a tipping point, and that some day, sooner rather than later, cancer will be treated with far greater odds for success and less toxicity to the patient.

This is the essence of progress. We thank you all for making that possible.

Barbara and Edward Netter, Co-Founders

PRESTIGIOUS MEDICAL INSTITUTIONS

MORE THAN $15 MILLION IN GRANTS

Message from the Chairman of the Scientific Advisory Council



The first five years at ACGT were devoted to the creation of a functioning foundation with a mission to support cancer gene therapy research, and to prove to the scientific and philanthropic communities that we are for real. We have indeed funded quality research in academic medical centers across the country year after year, and the community is both excited and appreciative of these efforts.

The foundation decided from day one to focus funding on young investigators who had not yet received a federal research grant. This is important because we need new ideas and we need new blood. The percentage of federal grants with principal investigators under the age of 35 has been decreasing precipitously over the years; at last count it was down to 4%. We stand to lose a whole generation of talented young researchers if support is not there during the most vulnerable time of their careers.

As the foundation has become established, we have recognized the need to increase support for clinical translational research. The human trial is the gatekeeper for future development of novel therapeutics. We can do all the laboratory research in the world, but until we conduct trials in patients, we will never know if the medication works and whether it is safe.

It is for this reason that ACGT now devotes one-half of grant funds for research projects moving into clinical translation. In the past, Investigator grants have been cancer-specific. In the last three years, we have funded leukemia, lymphoma, lung cancer and anti-angiogenesis translational grants. As we move forward, we hope to fund clinical trials for additional forms of cancer as well.

There has been exciting progress in the development of novel therapeutics for cancer gene therapy that are worthy of such support, particularly in the areas of immune-stimulation to reject cancer, blocking blood vessel formation in cancers to cause their shrinkage, and the use of viruses that kill cancer cells. Many projects have proven to work effectively and safely against multiple types of cancers in laboratory animals and are poised for clinical trials.

There are however obstacles to clinical trials, such as the multiple layers of review and approval processes in various funding agencies to support trials in gene therapy, which could cause delays in the development of these promising novel therapeutics. The American Society of Gene Therapy has established a new initiative to address these problems. The current president, Theodore Friedmann, MD, of UCSD School of Medicine, and the President-Elect, Arthur Nienhuis, MD, at St. Jude Children's Research Hospital, have proposed to all federal regulatory and funding agencies to develop a unified system to streamline the application and review processes.

I would like to take this opportunity to thank my fellow Scientific Advisory Council members and the many researchers who are working tirelessly to realize a better treatment for cancer. In the next five years, we hope to see the findings of scientific research move from the laboratory to human trials, and hopefully onto medical practice thereafter.

Dr. Savio Woo, Chair, ACGT Scientific Advisory Council
Chairman, Department of Gene and Cell Medicine,
Mt. Sinai School of Medicine, NY

American Society of Gene Therapy Position Statement on Clinical Trials

At present, there are two primary barriers to the initiation of trials in the academic setting: multiple, overlapping and lengthy levels of regulatory review, and increasing difficulty in obtaining entry-level RO1 and PO1 research grants. These obstacles have seriously dampened the enthusiasm of many academic centers to invest in the infrastructure needed for sustained efforts in gene therapy.

The Society recommends a unified approach to clinical trials to facilitate a sustained and efficient endeavor:

- Devise a structure for funding based on a single review decision.
- Evaluate all three phases of a trial at once by peer review–vector production, toxicity testing and conduct of the trial.
- Include periodic evaluation to ensure achievement of milestone goals prior to release of funds for subsequent study.
- Ensure access to laboratories such as the NGVL [National Gene Vector Lab] for vector production and quality control.

Dr. Theodore Friedmann, President of The Society observes that, "With the maturation of gene therapy, so too the mechanisms need to evolve. Harmonization and clarification of the funding stream with unified, appropriate time lines should benefit not only gene therapy trials, but the whole clinical enterprise as well."



Jack Roth, MD, F.A.C.S.

The University of Texas
M.D. Anderson Cancer Center,
Houston, TX
Professor and Chairman,
Bud Johnson Clinical Distinguished Chair
Department of Thoracic &
Cardiovascular Surgery
Professor of Molecular &
Cellular Oncology
Director, W.M. Keck Center
for Innovative Cancer Therapies
Chief, Section of Thoracic
Molecular Oncology

An Interview With Dr. Jack Roth, 2006 Appointed Member of the Scientific Advisory Council

Q. What has drawn you to cancer gene therapy?

I'm a cancer doctor by training, lung and esophageal cancer. It's very clear these malignancies are difficult to treat. Surgery alone is not the answer. When I was at the National Cancer Institute in the 1980's, it became evident that cancer in fact is a genetic disease, that cancer starts because of mutations or deletions in certain key genes in the cell. So the idea is really simple: if cancer is a disease of genes, we can replace that gene function to alter the growth of the cancers, and prevent them from spreading

Q. How soon will we see gene therapy in practice?

Cancer gene therapy is a reality now. There are agents in late stage clinical trials that have shown efficacy in treating patients. There is actually an approval for a therapy in China.

Q. What form of gene therapy has the most promise?

It is difficult to predict which form of gene therapy will be most promising. It's a little like a horse race. There is good scientific foundation for immunotherapy, and using genes to do this has been a major advance. We can use genes to control angiogenesis, the growth of blood vessels, which is important for cancer as well as other diseases. We can use genes to restore missing functions in cancer cells, to activate cell death. All are very promising, and it's likely that within the next five to ten years all of these therapies will come into clinical practice.

Q. What will be key to moving this science forward?

There is unfortunately not enough funding, and that threatens progress. No matter how good ideas are, no matter how exciting, if you don't have the funding, you can't do the experiments, you can't get to clinical trials. However, just funding all the research proposed is not going to do the job. You have to identify the most promising projects and make sure they get adequate funding. To do that requires scientific rigor, and this can be time consuming and often controversial, but it is the best way we have of identifying projects that merit funding.

Besides funding, there are increasingly difficult regulatory hurdles. Everyone is aware of this. The question is, who's going to do something first? We're going to need a paradigm shift, some very innovative approaches, to break down these barriers, so we can get things done faster.

Q. Are there any new models for research?

We can expect multi-institutional trials to be more prevalent in the future. We have a few here at M. D. Anderson right now. These make it possible to complete the trial more rapidly, because there is access to more patients. And the results are more reliable because they are tested in different settings.

However, early research, before we are able to standardize vectors and such, will be done by individual investigators, and that is vitally important. Funding is critical, and private, innovative foundations like ACGT will play a pivotal role.

2002	2003	2004	2005	2006
27 Institutions	36 Institutions	53 Institutions	61 Institutions	65 Institutions
45 Applicants	44 Applicants	70 Applicants	75 Applicants	84 Applicants
18 Finalists	21 Finalists	23 Finalists	30 Finalists	31 Finalists
3 Young Investigator Grants	5 Young Investigator Grants	4 Young Investigator Grants	4 Young Investigator Grants	3 Young Investigator Grants
		2 Investigator Grants	3 Investigator Grants	3 Investigator Grants

ACGT AWARDS PROCESS

1 Request for Applications (RFA)

- RFA invites scientific community to submit abstracts.
- The Scientific Advisory Council determines which abstracts conform to the RFA's research objectives.
- Qualified abstracts are invited to apply on-line.

2 Application Review

- Each application is reviewed by two peer reviewers using the NIH rating scale.
- The highest rated applications are distributed to each member of the Scientific Advisory Council.
- Two reviewers from the Scientific Advisory Council are assigned and rank each finalist, and final scores are assigned.
- The Scientific Advisory Council makes recommendations to the Board, and the Board makes the final decision and award announcement.
- Feedback is given to all applicants.

3 Contract Negotiation

- Once grantees are announced, the terms of the grant relationship are negotiated with the research institution and performance benchmarks are set.
- The agreement must include the 8 key items set forth in the application process.

4 Monitoring the Awards

- An annual review is conducted, and grant installments are made dependent upon achieving predetermined benchmarks, which conform substantially to aims outlined in the original proposal.

"There are few places that really encourage grants specifically designed to fund young investigators, so that it's very difficult to compete on a national level, especially at this time with funding being so tight. The grant from the Alliance for Cancer Gene Therapy was so instrumental in helping us complete the pre-clinical studies that were necessary for getting this trial started, that I don't know if we would be able to be at the point that we are right now without that assistance."

Thomas S. Griffith, PhD, University of Iowa, 2002 ACGT Research Fellow



NIH Clinical Center Director Dr. John I. Gallin and ACGT Co-founder Barbara Netter, with Dr. Judah Folkman, Childrens Hospital, Harvard Medical School, recipient of the first ACGT award for achievement, and ACGT Co-founder Edward Netter.

Fifth Anniversary Dinner Honors Dr. Judah Folkman

More than 500 scientists, research fellows, physicians and donors filled the ballroom at the Greenwich Hyatt Regency on September 28th in celebration of five years of progress and enthusiasm for the future of molecular medicine. The event yielded $1.8 million to fund critical research into cancer gene therapies.

Dr. John I. Gallin, Director of the National Institutes of Health Clinical Center, the largest clinical research hospital in the world, introduced Dr. Judah Folkman, a member of the ACGT Scientific Advisory Council, recipient of the first ACGT award for lifetime achievement, for discovery and visionary leadership in the field of angiogenesis.

"The first clinical trial for gene therapy was done at the institute in 1990," said Dr. Gallin. "The patient was a four year-old girl with adenosine deaminase deficiency, an inherited immune disorder that is deadly. Some of the genes contained in her white blood cells were broken. For her, gene therapy worked, and she's still doing well today."

"The race that medical researchers run is rarely a sprint," Dr. Gallin said. "It's a marathon in the truest sense. Success requires endurance, persistence and vision, and serendipity of circumstance or factors, all aligned when Dr. Judah Folkman first contemplated an intriguing idea in the early 1960's that tumors need blood to grow."

"The road has been long, often frustrating, but always exciting," Dr. Folkman said. "I thank the Alliance for Cancer Gene Therapy for putting their imprimatur on the value of persistence."

"We are so pleased to honor a scientist of Dr. Folkman's caliber," said Barbara Netter, co-founder of ACGT and event chairwoman. "Not only for his achievements, which are critical to the future of molecular medicine, but to reward tenacity in the face of great obstacles over the many years he has devoted to the science. We will win the war against cancer only because doctors like Dr. Folkman never give up, and only if they have the support they need to realize their aspirations."

Investigator Award Named for Dr. Folkman

ACGT Research Fellow Dr. George Coukos, Assistant Professor, Director of the Gynecological Oncology Laboratory at the University of Pennsylvania, was named the first recipient of the Dr. Judah Folkman Angiogenesis Award for Cancer Gene Therapy.



ACGT Co-founder Edward Netter with ACGT 2006 Investigator Dr. George Coukos, Assistant Professor, Director of the Gynecological Oncology Laboratory, Abramson Cancer Research Institute, University of Pennsylvania and Steve Solender, ACGT Supporter



ACGT Featured in *Philanthropy* Magazine

In the November/December issue of *Philanthropy* magazine, a publication of the *Philanthropy Roundtable,* a lead article entitled "Challenging the status quo in cancer research" featured the Alliance for Cancer Gene Therapy.

The article focused on ACGT research fellows Dr. Eckhard Podack at the University of Miami and Dr. Thomas Griffith at the University of Iowa.

Journalist Marshall Allen wrote that "ACGT strives to combine sound science with solid business principles and accountability to ensure a sound return on donor dollars. Grants are given to individual scientists, not institutions, out of a belief that it's the researchers themselves who are the visionaries."

The article quoted board member Eric Rothfeld on the foundation's business approach to philanthropy: "The most donor-friendly aspect of ACGT, he says, is that 100 percent of foundation funds go to research. Separate funding covers all operating expenses. This is not an organization that's building an administrative bureaucracy."

Board member John Adler was also cited regarding the importance of focusing on research closer to the clinical trial phase. "Funding research at this stage means it may be only five years – instead of 15 – until breakthroughs turn into life-saving drugs."



ACGT Executive Director Margaret Cianci with 2004 Young Investigator Dr. Jain Yu, Assistant Professor Department of Pathology, University of Pittsburgh School of Medicine and 2005 Investigator Hyam I. Levitsky, Johns Hopkins University School of Medicine.

HIGHLIGHTS

At the American Society of Gene Therapy Annual Meeting

ACGT Board members, senior staff and members of the Scientific Advisory Council attended the American Society of Gene Therapy's 9th annual meeting in June in Baltimore, Maryland where Council members and Research Fellows presented papers, deliberated with fellow researchers and medical practitioners and strengthened coalitions in support of cancer gene therapies. The Society is the largest medical professional organization in the world, representing researchers and scientists dedicated to the discovery and application of all forms of gene therapy.

"There was a sense of achievement at this meeting, about gene therapies as the future for many diseases that so desperately need new forms of treatment and new hope," said ACGT Executive Director, Margaret Cianci.

Several of our Research Fellows are members, including Dr. Michel Sadelain who serves on the Board, and several are committee members, including Dr. Savio Woo, past-president, who chairs the Public Education and Outreach Committee.

Over 1000 abstracts were presented during the 4-day conference, of which over 100 were concerned with cancer gene therapies. Of these, 19 of our Research Fellows or Scientific Advisory Council members were authors.

ACGT Wins Seal of Approval from Wise Giving Alliance

The BBB Wise Giving Alliance – a merger of the National Charities Information Bureau and the Council of Better Business Bureaus' Foundation – grants a coveted seal of approval only to charities which meet their highest standards regarding governance, effectiveness, public communications and financial management, notably:

- Truthfulness of representation
- Adherence to applicable laws and regulations
- Regular oversight by the Board of Directors
- Adequate measures of effectiveness
- Respect for donor privacy and intent
- Full disclosure related to operations, programs and finances.

"National charities that display the BBB Wise Giving Alliance seal can do so with pride," says Art Taylor, President/CEO. "Not only are they attesting to their organization's adherence to sound standards, they are helping to increase donor confidence and strengthen public trust in giving."

We are grateful to these prestigious institutions for their support of the 5th Anniversary Dinner, and their commitment to cancer gene therapy research

Abramson Cancer Center & University of Pennsylvania Health System	Philadelphia, Pennsylvania
Columbus Children's Research Institute	Columbus, Ohio
Duke University Medical Center	Durham, North Carolina
Harvard Medical School	Boston, Massachusetts
Memorial Sloan-Kettering Cancer Center	New York, New York
Moores UCSD Cancer Center	San Diego, California
Mount Sinai School of Medicine	New York, New York
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins	Baltimore, Maryland
St. Jude Children's Research Hospital	Memphis, Tennessee
University of Miami Miller School of Medicine	Miami, Florida
University of Pittsburgh Cancer Institute	Pittsburgh, Pennsylvania
The University of Texas MD Anderson Cancer Center	Houston, Texas



"DNA in our cells is the blueprints of our life. If there is any mistake or changes in that blueprint, that can result in disease. So our goal is to actually be able to go back and correct those blueprints back to their original form. Being able to take a new approach at a problem that has been so stubborn to being solved, that's the challenge. And we have hoped that gene therapy will open completely new avenues of research and new ways of treatment. It's a hard road for sure, as is any new approach. But I believe in it, and that's why I've worked on it for so many years and will continue to do so."

Suzie Pun, PhD, Assistant Professor, University of Washington, 2004 ACGT Research Fellow

ACGT Research Fellow
Dr. Michel Sadelain
Prepares for Human Trial



Michel Sadelain, MD, PhD

Director, Gene Transfer and Somatic Cell Engineering Facility
Head, Gene Transfer and Gene Expression Laboratory
Memorial Sloan-Kettering Cancer Center
New York, NY

Michel Sadelain, MD, PhD, a 2004 Research Fellow at Memorial Sloan Kettering Cancer Center in New York, awaits final approval to a Phase I clinical trial for victims of chronic lymphocytic leukemia. Pending a green light from the Investigational New Drug [IND] committee of the FDA, Sadelain hopes to begin enrolling patients in the spring.

The trial is based on successful results of a project funded by ACGT to assess the therapeutic potential of genetically targeted T-cells. Sadelain's team demonstrated that T-cells can be redirected to recognize the CD19 antigen and eradicate established systemic tumors borne by immune-deficient mice, demonstrating for the first time that genetically modified human T-cells can induce durable remissions in an in-vivo setting.

In the last eighteen months, Sadelain has focused on securing approvals necessary to implement the trial. This is an arduous process that involves hundreds of hours for the principal researchers and many more hours by both support and oversight professionals, including clinical experts, gene transfer and cell therapy scientists, and quality assurance and regulatory specialists.

"There are no fees for trial approval, but there are a lot of expenses incurred to validate assays and prepare documentation and materials. A lot of people spend a lot of time on securing the mandated approvals."

Approvals are required on the national level by the Recombinant DNA Committee [RAC] concerned primarily with scientific, ethical and legal issues, and the FDA, which also looks in great detail at the clinical design, biosafety, vector and cell manufacturing, and patient monitoring. In addition, the sponsoring institution's review board [IRB] and the Institutional Biosafety Committee [IBC] must approve the project. If significant changes are required to the study design anywhere in the chain of approvals, the protocol may have to go back to committees and agencies for further review, delaying the start date.

In addition, Memorial Sloan-Kettering Cancer Center requires that every departmental committee that has a faculty member involved in the trial must also grant approval. "On average, this involves 3-5 committees, who are primarily concerned with clinical, ethical and financial issues."

Memorial Sloan-Kettering is one of a handful of centers that manufactures vectors, which is an asset for controlling product quality, cost efficiency and governance. Sadelain says they have devised a process to introduce the gene in patient T-cells using a nearly closed system, which is a safer procedure, another asset.

Sadelain is looking forward to enrolling 24-30 patients for the study, which is first and foremost concerned with safety. "This is a dose-escalation trial, with great attention to toxicity. We will be enrolling patients for two years and carefully monitoring their progress." After giving informed consent, patients are enrolled, their cells processed, tested, and then infused back into the patient. Toxicity levels will determine if the doses can be increased. Additional patients will be enrolled as needed.

"This trial involves novel practices. There is no cookbook to tell you how to generate safe and efficacious, genetically enhanced T-lymphocytes. This is the future."

ACGT RESEARCH GRANT AWARDS

2006 Investigators

Roberto Cattaneo, PhD
Professor, Director, Virology and Gene Therapy Graduate School
Mayo Clinic College of Medicine



Gene Therapy for Lymphoma and Leukemia
Studies in recent years have documented the lytic effects of various viruses on many human cancers, and the study and re-engineering of oncolytic viruses is intensifying. Recombinant measles viruses [MV] appear to be ideal vectors for lymphoma treatment, as wild-type MV infection occasionally induces lymphoma regression in humans. “We plan to produce viruses that replicate selectively in transformed lymphocytes, viruses with modulatable cytotoxicity, and viruses with a targeted envelope. Eventually we will combine the characteristics of the most effective viruses into a ‘second generation’ virus that is armed and targeted.”

George Coukos, MD, PhD
Assistant Professor, Director, Gynecological Oncology Laboratory
University of Pennsylvania Abramson Family Cancer Research Institute
Recipient of the Dr. Judah Folkman Angiogenesis Award for Cancer Gene Therapy



Anti-angiogenic Gene Therapy for Ovarian Cancer
This study will test the central hypothesis that T-body cell therapy is the only form of anti-angiogenic gene therapy immediately translatable clinically that can deliver sustained vascular disrupting agent-type effect which is tumor-specific, self-amplifying in vivo and endowed with memory. The research will generate and test in vitro human lymphocytes engineered to recognize and attack tumor blood vessels, and conduct a phase I trial to test their safety and anti-tumor efficacy in patients with advanced recurrent ovarian and peritoneal cancers. “Development and delivery of T-cells directed against tumor vascular targets offers multiple theoretical advantages: it can be highly specific, efficient and sustained in time. In addition, it has the potential for significant antigen-induced amplification in vivo and is the only one that can provide long-term memory.”

Eckhard Podack, MD, PhD
Professor, Department Head, Microbiology and Immunology
Miller School of Medicine of the University of Miami



Gene Therapy for Lung Cancer
The proposed study will utilize a novel approach to a vaccine for lung tumors, based on a genetically modified, secreted form of heat shock protein. These tumors are ideal targets for immunotherapy, a gene therapy that stimulates the body’s immune system to recognize and attack cancer cells. The vaccine is comprised of lung tumor cells that secrete hsp-gp96, which facilitates the generation of killer cells against the tumor. “Initial in vitro data, and with experimental mice, indicates that a vaccine using these proteins is over one million fold more efficient in the generation of killer cells. In addition, these properties allow us to study how gp96 induces or restores immunity that is suppressed in the presence of existing tumors.”

Up to $1 million Investigator grants, made possible by the ACGT Fund for Advancement, are awarded to researchers conducting 3-5 year projects entering clinical translation.

Up to $500,000 Young Investigator grants are awarded by the Fund for Discovery for tenure-track assistant professors doing groundbreaking research to uncover new methods of treatment.

In five years, a total of 318 applications, representing 105 different institutions, have been submitted for review, with 123 finalists resulting in 27 grants.

2006 Young Investigators

Maciej S. Lesniak MD
Director, Neurosurgical Oncology and the University of Chicago Brain Tumor Center



Glioblastoma Multiforme
Glioblastoma multiforme (GBM) is the most common primary malignant tumor of the adult central nervous system. Despite recent advances in therapy, the median survival rate remains measured in months rather than years. The recurrent nature of the disease has prevented the development of effective long-term therapies. Oncolytic viruses that are replication competent in tumors, but not in normal cells, represent a novel approach for treating neoplastic diseases. The goal of this project is to develop a virus that utilizes a glioma specific promoter and binds to a receptor that is over-expressed on malignant brain tumors. Preliminary data suggest that a replication defective form of the adenovirus shows significantly greater transgene expression than a wild-type virus. “We therefore propose to create a novel oncolytic vector that utilizes transductional and transcriptional control to assess efficacy against malignant glioma in vitro and in vivo.”

Kah-Whye Peng PhD
Associate Professor, Senior Associate Consultant, Molecular Medicine Program
Mayo Clinic Cancer Center



Multiple Myeloma
Live attenuated Edmonstron strain measles virus [MV] shows promising anti-tumor activity against several human cancers. There are currently three Phase I clinical trials underway to assess safety, with applications in ovarian cancer, glioma and multiple myeloma. However most patients have been immunized against the MV and have anti-viral antibodies that can inactivate the virus, limiting systemic MV virotherapy for metastatic diseases. We know that MV trafficks in white cells and uses them as vehicles for dissemination in the human host during the natural infection. Thus, we propose to use cells as vehicles to carry the virus to the tumor site, protecting the virus while it infects the tumor cells to induce cell death. The ability of the cell carriers to support robust virus amplification is an added bonus. “In the end, we hope to have a feasible and effective clinical protocol based on our findings to treat relapsed multiple myeloma.”

Harald Sauthoff MD
Assistant Professor of Medicine, Pulmonary & Critical Care Medicine, New York University



Lung and Breast Cancer
Available data indicate that adenoviral cancer gene therapy, using tumor suppressor or other genes, is safe and could be highly effective for many types of cancer. In cell culture experiments, cancer cells can easily be eliminated with adenoviral vectors. However, in solid tumors, efficient viral gene transfer has been extremely difficult to achieve, and results from human trials show only modest response rates. Limited distribution of the virus, even with replication-competent viruses, has emerged as one of the main obstacles for adenoviral-mediated cancer gene therapy. We are testing the hypothesis that protein transduction technology can improve adenoviral vectors for the treatment of cancer. Protein transduction domains are short peptides that can penetrate intact cell membranes. We are investigating if adenoviral expression of therapeutic peptides fused to a protein transduction domain will mediate wider intratumoral distribution of the therapeutic agent and lead to more efficient cancer therapy. “Delivery of transducible peptides with adenoviral vectors is a new strategy that could find broad application for cancer gene therapy.”

ACGT Research Fellows 2002 – 2006

2006 Fellows

Roberto Cattaneo, PhD
Mayo Clinic College of Medicine
Lymphoma/Leukemia
Tumor specific replicating virus

George Coukos, MD, PhD
University of Pennsylvania Abramson Family Cancer Research Institute
Ovarian and Peritoneal Cancer
Anti-angiogenesis
Recipient of the Dr. Judah Folkman Angiogenesis Award for Cancer Gene Therapy

Maciej S. Lesniak, MD
University of Chicago
Brain Cancer
Tumor Targeting and Vector Development

Kah-Whye Peng, PhD
Mayo Clinic Cancer Center
Myeloma
Tumor Specific Replicating Viruses and Bacteria

Eckhard Podack, MD, PhD
University of Miami Miller School of Medicine
Lung Cancer
Immune-mediated gene therapy

Harald Sauthoff, MD
New York University
Breast/Lung Cancer
Tumor Targeting and Vector Development

2005 Fellows

Biao He, PhD
Pennsylvania State University
Breast Cancer
Tumor specific replicating virus

Thomas J. Kipps, MD, PhD
University of California, San Diego, Moores Cancer Center
Lymphoma/Leukemia
Immune-mediated gene therapy

Hyam I. Levitsky, MD
Johns Hopkins University School of Medicine
Lymphoma/Leukemia
Immune-mediated gene therapy

Miguel Sena-Esteves, PhD
Massachusetts General Hospital/Harvard Medical School
Brain Cancer
Oncogenesis

Koji Tamada, MD, PhD
Johns Hopkins University School of Medicine
Lymphatic systems
Immune-mediated gene therapy

Xianzheng Zhou, MD, PhD
University of Minnesota – Twin Cities
Blood, Lymphoma/Leukemia
Immune-mediated gene therapy

Yiping Yang, MD, PhD
Duke University
Lymphoma/Leukemia
Immunotherapy

2004 Fellows

Chien-Fu Hung, PhD
Johns Hopkins University School of Medicine
Ovarian Cancer
Immunotherapy

Mukesh Jain, MD, FAHA
Case Western Reserve University
Metastatic Cancer
Anti-angiogenesis

Carl H. June, MD
University of Pennsylvania Abramson Family Cancer Research Institute
Lymphoma/Leukemia
Immune-mediated gene therapy

Suzie Pun, PhD
University of Washington
Metastatic Cancer
Targeted non-viral delivery
Recipient of Patricia Zoch Tate Gene Therapy Award

Michel Sadelain, MD, PhD
Memorial Sloan Kettering Cancer Center
Lymphoma/Leukemia
Immune-mediated gene therapy

Jian Yu, PhD
University of Pittsburgh School of Medicine, Hillman Cancer Center
Lung Cancer
Oncogenesis

2003 Fellows

Laurence Cooper, MD, PhD
University of Texas, MD Anderson Cancer Center
Leukemia/Lymphoma
Immune-mediated gene therapy

Timothy Lane, PhD
University of California, Los Angeles
Breast Cancer
Anti-angiogenesis
Recipient of The Kimberly Lawrence Netter Gene Therapy Breast Cancer Award

Todd R. Reilly, PhD
Johns Hopkins University [thru 2006]
Breast Cancer
Immune-mediated gene therapy

Katherine Ryman, PhD
Louisiana State University Medical Center, Shreveport
Prostate Cancer
Tumor specific replicating viruses

Robert Vonderheide, MD, D.Phil.
University of Pennsylvania Abramson Family Cancer Research Institute
Neuroblastoma
Immune-mediated gene therapy

2002 Fellows

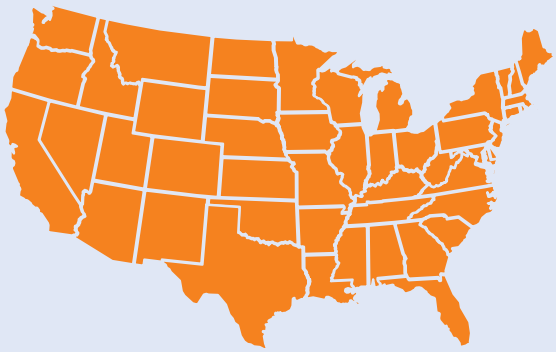
Jeffrey S. Bartlett, PhD
Children's Research Institute, Columbus
Ovarian Cancer
Vector Development

Andrew M. Davidoff, MD
St.Jude Children's Research Hospital
Neuroblastoma
Anti-angiogenesis

Thomas S. Griffith, PhD
University of Iowa
Prostate Cancer
Immune-mediated gene therapy

Over the past 5 years, ACGT has received applications from the following institutions pursuing cancer gene therapy :

Albany Medical Center
Albert Einstein School of Medicine
Auburn University
Aurora Heath Care, Inc
Baylor College of Medicine
Baystate Medical Center
Beth Israel Deaconess Medical Center
Brigham and Women's Hospital, Inc./ Harvard University Medical School
Case Western Reserve University
Cedars-Sinai Medical Center
Children's Hospital Boston
Children's Hospital, Los Angeles
Children's Hospital, Philadelphia
City of Hope National Medical Center
Cold Spring Harbor Laboratory
Columbus Children's Research Institute
Dana-Farber Cancer Institute
Duke University School of Medicine
Eastern Virginia Medical School
Fred Hutchinson Cancer Research Center
Georgetown University Medical Center
Henry Ford Health System
Illinois Institute of Technology
Indiana University School of Medicine
Jackson Laboratory
Johns Hopkins University School of Medicine
La Jolla Institute for Allergy & Immunology
Louisiana State Health & Sciences Center
Lovelace Respiratory Research Institute
M.D. Anderson Cancer Center
Marshall University Research Corporation
Massachusetts General Hospital/Harvard University Medical School
Mayo Clinic/ Foundation
Memorial Sloan Kettering Cancer Center
Methodist Hospital Research Institute
Moffitt Cancer Center, University of Southern Florida
Montefiore Medical Center
Mount Sinai School of Medicine
National Jewish Medical & Research Center
New Jersey Medical School (UMDNJ)
New Jersey Medical School (UMDNJ), Robert Wood Johnson Medical School
New York University School of Medicine
Northwestern University Feinberg School of Medicine
Ohio State University College of Medicine
Oregon Health and Science University School of Medicine
Penn State University College of Medicine
Pennsylvania State University
Rockefeller University
Roger Williams Hospital
Roswell Park Cancer Center
Rutgers,The State University of New Jersey
Salk Institute for Biological Studies
Southern Methodist University
St. Louis University Medical Center
St. Jude Children's Research Hospital
Stanford University School of Medicine
SUNY, State University of New York, Buffalo School of Medicine
SUNY, State University of New York, Downstate
SUNY, State University of New York, Stony Brook School of Medicine
Texas Tech University
Thomas Jefferson University, Kimmel Cancer Center
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Tulane University
University of Alabama, Birmingham School of Medicine
University of Arkansas for Medical Sciences
University of California, Berkeley School of Medicine
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University of South Carolina Research Foundation
University of Southern California, Keck School of Medicine
University of Texas, Austin
University of Toledo
University of Utah School of Medicine
University of Washington School of Medicine
University of Wisconsin Medical School
Van Andel Research Institute
Vanderbilt University Medical Center
Virginia Commonwealth University
Wake Forest University School of Medicine
Washington University in St. Louis
Wayne State University School of Medicine
Yale University School of Medicine



"I am very excited about what's going on now. And I think that some of these findings are going to translate into treatments, hopefully soon, to affect therapy for patients which actually can make a difference. I believe that in my lifetime we will be able to see this become an effective arsenal against cancer. I'm an eternal optimist; you have to be to be a researcher, but I've seen some very exciting developments."

Thomas J. Kipps, MD, PhD, University of California, San Diego, 2005 ACGT Research Fellow



In Texas, a lung cancer survivor thanks gene therapy for her life

Bunny Morrow of Texas, at 72 years of age, has found a new lease on life. Nearly four years after she discovered lung cancer so advanced it had wrapped around her vocal chords, she is alive and well and volunteers helping patients navigate their treatment at the Mary Crowley Oncology Center at Baylor University, where she successfully participated in a cancer gene therapy trial.

"I feel a real connection to them," Morrow said recently. "And if anyone asks, I tell them that gene therapy is simply the best. Thank God I was able to be in that trial."

There was no cancer in Morrow's family history and although she had smoked at one time, she quit many years earlier. Given the spread of the cancer and positive lymph nodes, surgery was not the best option, although her upper left lobe was removed and she underwent early chemotherapy to shrink the tumor so she might meet the trial protocol. "My surgeon didn't want me to fall through the cracks."

"They took my cancer cells and irradiated them, and then injected them back into my body so my immune system would kick in," Morrow said. "I had about 16 injections, and absolutely no side effects beyond a couple of allergic reactions that Benadryl took care of. No problem."

Morrow has an annual PET scan but no other medical requirements. She bakes muffins for trial patients [her specialty is cranberry] and is the best possible example of what other trial participants might expect. "They have made so much progress, it's amazing."

2006 PROGRESS REPORT

"The problem is many times that you're just not treating one simple abnormality in the cancer cell, but you have many things to take care of. There probably won't be one single form of gene therapy– one magic bullet if you will. There will be several avenues of attack. And as opposed to saying someone has breast cancer, you will define five or six different kinds of breast cancer with different gene abnormalities, each treated in a slightly different way."

Robert Martuza, MD, F.A.C.S., Chief of Neurological Services Massachusetts General Hospital, Harvard Medical School, ACGT Scientific Advisory Council Member

At the University of Pennsylvania, a cold virus wages war on Mesothelioma



Karen Marcum, 65, made her way from Texas to the University of Pennsylvania to wage battle against Mesothelioma. The deadly lung cancer, hard to detect and one of the most merciless, is primarily caused by exposure to asbestos or similar materials, although Marcum says she's not sure where it came from.

"I was the 5th member of my family to be diagnosed," she said when cancer was discovered in both lungs. Treatment options are limited and she did not qualify for a pleurectomy, surgery to remove the outermost lining around the lungs, which is often the only line of attack. "Maybe that was a good thing. I don't know the quality of life I might have had," Marcum said.

Instead she underwent chemotherapy in early 2006 while awaiting entry into a clinical trial utilizing a gene drug developed by Biogen Idec that utilizes a cold virus genetically altered to carry the gene for interferon beta, a natural human protein that marshals the immune system.

"One dose, then another two weeks later," said Marcum, who took up residence for four months in Philadelphia. Following treatment, she had monthly check-ups, but as of January of this year, she was told she will not require evaluation for another six months.

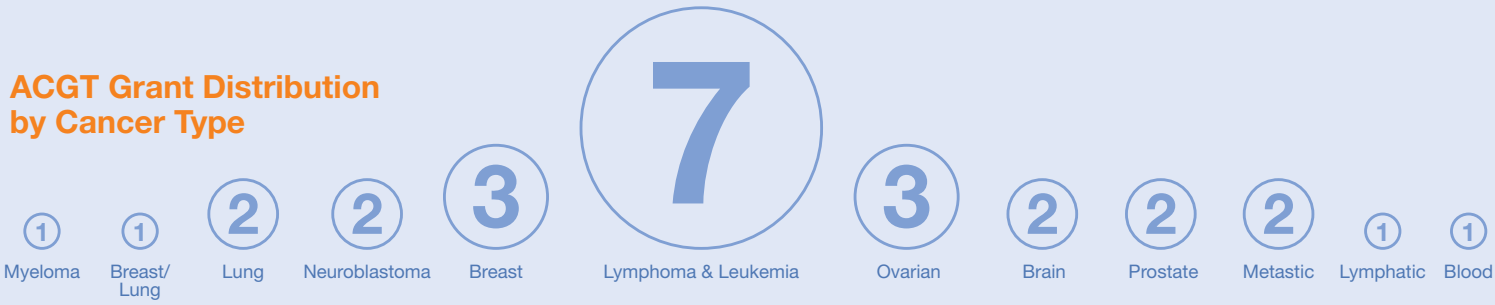
"I'm not in remission and I'm not cured," Marcum said. "But they tell me I'm stable and the tumors have definitely shrunk. I've seen pictures of my lungs."

Marcum, like so many gene therapy participants, reported no reaction to the treatment. "No side effects at all. I suffered neuropathy from the chemo, but nothing from gene therapy."

"This was a wonderful experience. Such caring people," Marcum said.

In March, twin grandsons were born, and Karen Marcum was there to welcome them.

ACGT Grant Distribution by Cancer Type



27 grants awarded to date



NIH Director, Dr. Elias A. Zerhouni

At the NIH, gene therapy successfully destroys advanced Melanoma

At the National Cancer Institute [NCI] of the National Institutes of Health [NIH] a team of researchers successfully utilized a form of immune-mediated therapy to destroy cancer cells in melanoma, a deadly form of skin cancer. The trial demonstrated sustained regression of advanced metastatic cancer using genetically engineered white blood cells from patients in the study. These blood cells were able to recognize, attack and destroy cancer cells, the very essence of gene therapy, without any side effects or contraindications.

"These results represent the first time gene therapy has been used successfully to treat cancer," said NIH Director, Elias A. Zerhouni, MD. "Moreover, we hope it will be applicable not only to melanoma, but also for a broad range of common cancers."

In a process called adoptive cell transfer, the most aggressive tumor-killing cells are isolated from the patient's lymphocytes, multiplied in the laboratory, and reintroduced to patients.

"We are currently treating advanced melanoma patients using adoptive transfer of genetically altered lymphocytes, and we have now expressed other lymphocyte receptors that recognize breast, lung and other cancers," said Steven A. Rosenberg, MD, PhD, lead researcher in the NCI study.

Researchers said they hope the same approach can fight breast, lung and other cancers. Rosenberg reported that they are seeking regulatory approval to test the technology in patients with other cancers.

For more information, go to our website: www.acgtfoundation.org

At M. D. Anderson, dual gene therapy suppressors pack twice the punch against cancer

At the University of Texas M. D. Anderson Cancer Center, a trial utilizing combined targeted gene therapy vastly reduced human non-small cell lung cancer tumors in mice.

Two tumor-suppressing genes given together intravenously proved far more powerful than separately, reducing the number of tumors by 75% and the weight by 80%. The genes, wrapped in nanoparticles, were p53, well-known tumor suppressors that cause defective cells to commit suicide, a process known as apoptosis, that is often inhibited in cancer cells.

"We certainly hope this approach will be more effective, but we also think it's likely to be much less toxic, with fewer side effects, than other types of combined cancer therapy," said Dr. Jack Roth, chair of the M. D. Anderson Department of Thoracic and Cardiovascular Surgery, and member of the ACGT Scientific Advisory Council. "These genes don't have much effect on normal tissue or normal cells when they are over-expressed, only cancer cells."

The nanoparticles are being tested alone in a phase 1 safety and dose-escalation clinical trial with patients with advanced lung cancer that has spread to other organs. Next step: full-scale human clinical trials.

Financial Report

April 30, 2006 and 2005

CONDENSED STATEMENTS OF ACTIVITIES	2006	2005
Support and revenue:		
Contributions	$ 4,176,363	$ 3,334,719
Contributions for administrative expenses (specially designated)	92,404	47,000
Contributed services	181,057	145,864
Interest and dividend income	82,782	47,006
Realized and unrealized gains on investments, net	218,159	196,142
TOTAL SUPPORT AND REVENUE	**4,750,765**	**3,770,731**
Expenses:		
Program services:		
Research grants and awards	3,946,262	3,425,510
Supporting services	213,852	148,439
TOTAL EXPENSES	**4,160,114**	**3,573,949**
Increase in total net assets	590,651	196,782
Total net assets at beginning of year	1,341,505	1,144,723
TOTAL NET ASSETS AT END OF YEAR	**$ 1,932,156**	**$ 1,341,505**

CONDENSED STATEMENTS OF FINANCIAL POSITION	2006	2005
Assets:		
Cash and cash equivalents	$ 1,344,978	$ 1,196,688
Investments, at fair value	3,197,082	2,515,608
Contributions receivable	2,891,197	1,507,304
TOTAL ASSETS	**7,433,257**	**5,219,600**
Liabilities and net assets:		
Liabilities:		
Grants payable	5,486,635	3,877,495
Accounts payable and accrued expenses	14,466	600
TOTAL LIABILITIES	5,501,101	3,878,095
TOTAL NET ASSETS	**1,932,156**	**1,341,505**
TOTAL LIABILITIES AND NET ASSETS	**$7,433,257**	**$5,219,600**

Alliance for Cancer Gene Therapy, Inc.'s complete audited financial statements are available upon request.

The Board of Directors has set a funding goal of $24 million over the next five years. To date, $3.5 million has been raised, $1.8 from the Fifth Anniversary Dinner. In an effort to balance ACGT's research portfolio, funds raised will be equally shared between Investigators pursuing clinical trials and Young Investigators involved in early scientific discovery. This distribution of funds satisfies the Board's commitment to the acceleration of cancer gene therapy research, while continuing to provide opportunities for young scientists to pursue innovation.

Many thanks to our generous donors who make it possible for ACGT to fund critical cancer gene therapy research

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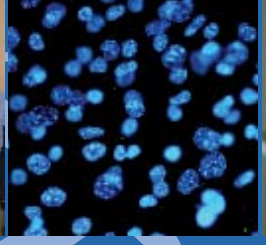
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The letters A [Adenine] C [Cytosine] G [Guanine] and T [Thymine] make up the genetic code of all genes.

"Now we believe that the DNA is a code. That is, the order of the bases (the letters) makes one gene different from another gene (just as one page of print is different from another). You can see how Nature makes copies of the genes. Because if the two chains unwind into two separate chains, and if each chain then makes another chain come together on it, then because A always goes with T, and G with C, we shall get two copies where we had one before. In other words, we think we have found the basic copying mechanism by which life comes from life."

– Francis Crick, PhD
Co-Discoverer of the Genetic Code, March 17, 1953