

CLARK UROLOGICAL CENTER

N E W S L E T T E R

KIDNEY CANCER PROGRAM OFFERS NEW HOPE TO PATIENTS; RESEARCH, EXPERIMENTAL OPTIONS REDEFINE TREATMENT

Pioneering UCLA Group Recognized as World Leader



Members of the UCLA Kidney Cancer Program, front row (left to right): Gang Zeng, PhD; Fran Rosen; Melanie Ozaki; Annette Tan; Carol Marks; Vernalie Deirmenjian; Allen Wang; Cindy Melo. Back row (left to right): Nazy Zomorodian, MSN, NP; Tracey Krupski, MD; Randy Caliliw; Robert A. Figlin, MD; Arie Beldegrun, MD; Ken-ryu Han, MD; Nicolette Janzen, MD; Hideki Mukouyama, MD.

Approximately 32,000 people are diagnosed with kidney cancer in the United States each year, and for many of these patients, the prognosis is poor. If detected in its early stage, kidney cancer can be cured surgically through a nephrectomy (removal of the diseased kidney). But one in three kidney cancer patients has metastatic disease by the time of diagnosis, and roughly half of those who have surgery for less advanced disease eventually relapse. For patients with metastatic renal cell carcinoma – the most common form of kidney cancer – the three-year survival rate is less than 5 percent.

Kidney cancer doesn't respond to standard chemotherapy, leaving only one

FDA-approved drug treatment for patients with advanced disease: interleukin-2 (IL-2), which stimulates the immune system to fight the cancer. Pioneering work at UCLA in the 1990s resulted in the first reports of durable remissions for a small subset of metastatic kidney cancer patients treated with immunotherapy in combination with nephrectomy. IL-2 has produced the best results; still, success rates are modest: 15-20 percent of patients benefit from the drug, and many are unable to tolerate it due to its high toxicity.

"For the majority of kidney cancer patients, conventional therapies are inadequate," says Robert Figlin, MD, professor of clinical urology and medicine at UCLA.

"The best options for most kidney cancer patients currently are experimental."

The UCLA Kidney Cancer Program, headed by Drs Figlin and Arie Beldegrun, professor of urology and chief of urologic oncology, is the recognized leader in defining these experimental options. The 12-year-old program, which includes cutting-edge basic research and an integrated team of physician-scientists from urologic oncology and medical oncology, has played a major role in the design of clinical trials for kidney cancer throughout the world – and is currently making significant progress as it moves from therapies that broadly stimulate the immune system to those that target the kidney cancer. "We have been

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able, for the first time in the history of this lethal disease, to induce a complete disappearance of all metastatic deposits and, in fact, cure patients who otherwise would have only a few months to live,” says Dr. Belldgrun. “Now they are alive and resuming normal activities for years. Unfortunately, though, only a small number of patients can now be cured with immunotherapy, and side effects are significant. Therefore, our laboratory is designing the next generation of therapies that are molecular-based and targeted specifically to kidney cancer cells. These approaches will be less toxic and more specific.”

Among the strategies that are being pursued:

Target-Specific Antibodies

The UCLA Kidney Cancer Program is testing antibodies to the epidermal growth factor receptor (EGFR) in a Phase II clinical trial. “This is a molecular target that is available on many kidney cancer patients,” says Dr. Belldgrun. By blocking this receptor, the UCLA researchers hope to halt the growth of the cancer.

Angiogenesis Inhibitors

One experimental approach that has attracted a great deal of interest in the fight against a number of cancers is to target the process by which tumors supply themselves with the nutrients and oxygen they need via the development of new blood vessels. So-called angiogenesis inhibitors attempt to cut off the tumor’s blood supply to starve – and, perhaps, kill – the cancer. “Kidney cancers in particular are very vascular,” Dr. Belldgrun explains. “They have a huge number of blood vessels.” His team is now targeting the proliferation of blood vessels in kidney cancer patients through agents that block the vascular endothelial growth factor (VEGF).

Dendritic Cell Therapy

Drs. Belldgrun and Figlin were among the first to use dendritic cell therapy – combining the patient’s tumor with powerful dendritic cells to form a vaccine against

the cancer. They are now preparing a clinical trial in which the patient’s dendritic cells will be fused electromagnetically with his cancer cells, “educating” the dendritic cells to go after the cancer once returned to the body.

The program has also taken steps to capitalize on the UCLA kidney cancer database – one of the nation’s largest, with more than 1,500 patients – by developing a system for staging and predicting survival of patients with renal cell carcinoma, as well as an algorithm that assigns patients with localized and metastatic kidney cancer into low-, intermediate-, and high-risk groups, each with specific variables that can predict prognosis. The UCLA Integrated Staging System (UISS) is now being used to identify optimal treatment approaches for individual patients. “Kidney cancer patients are a heterogeneous group,” notes Dr. Belldgrun. “One group of patients may be excellent candidates for treatment A, while others are better for treatment B or C. The UISS will enable us to stratify patients to receive the most appropriate therapy. We hope to customize the best therapy for the individual kidney cancer patient.”

Understanding the biology of kidney cancer is the key to designing better therapies, Dr. Figlin explains. Fewer resources have been devoted to this effort than to more common cancers, but private philanthropy has helped to propel the UCLA program forward. “The problem has been that unlike other tumors, kidney cancer hasn’t had identifiable tumor antigens against which we could develop a vaccine,” says Dr. Belldgrun. Among other things, the UCLA Kidney Cancer Program database is being used to identify tumor “markers” that would provide prognostic information as well as new targets for treatment.

“We’re beginning to identify very specific targets within the cancer and develop molecules that address those targets,” says Dr. Figlin. “There’s no question but that the future of kidney cancer will be in the experimental trials, not in the existing therapies. Patients diagnosed with kidney cancer should immediately explore options for the type of surgery they should get and what can be done afterward that might be better than conventional therapy.”

For more information on the UCLA Kidney Cancer Program and clinical trials, visit www.uclakidneycancer.com.

About Clinical Trials

Clinical trials are critical to improving the treatment of medical conditions because they lead to better therapies and higher standards of care. In the United States, all new drug therapies and most medical and surgical treatments must be tested for safety and efficacy. These patient-based studies, which follow strict protocols and are overseen by the Food and Drug Administration (FDA), occur in three successive phases:

In Phase I trials, investigators test the feasibility and toxicity of a treatment.

In Phase II, they seek to confirm the results of Phase I and establish the therapeutic value of the treatment.

In Phase III, the efficacy of the treatment is compared to that of the currently used standard(s) of care.

Once a new therapy has successfully progressed through all three phases, it is approved as a standard treatment.

A list of open clinical trials offered by the UCLA Department of Urology appears on the department’s Web site: www.urology.medsch.ucla.edu. In addition, information specific to the Kidney Cancer Clinical Trials Program is available at www.uclakidneycancer.com.

ON THE FRONT LINES OF CLINICAL TRIALS: NURSES MONITOR TREATMENTS, ADDRESS PATIENTS' CONCERNS

Experimental Therapies Draw Patients from Near and Far

Clinical trials – carefully controlled studies to determine whether new drugs or treatment procedures are safe and effective – provide opportunities for patients to benefit from state-of-the-art therapies years before they are available to the general public. In some cases, such as for certain cancer patients, they may offer hope after conventional treatment has failed.

“One of the biggest draws to a leading academic center such as UCLA is that, besides having conventional treatments available, patients have cutting-edge alternatives,” says Nazy Zomorodian, RN, MSN, NP, CCRC, a urology nurse practitioner and director of the Clark Urological Center’s Clinical Trials Office, which administers trials in prostate, kidney and bladder cancer; male infertility and erectile dysfunction; female urology; female sexual medicine; and pediatric urology. Moreover, she notes, a leading center such as UCLA, which is approached by many companies seeking to test a new therapy, has the luxury of being able to select those trials that the investigators believe are most promising.

Patients’ rights are closely protected whenever they decide to enroll in a clinical trial; they are given extensive consent forms that explain in lay language the potential risks and benefits of participating in the trial, Ms Zomorodian says. “We discuss with them what alternatives would be available if they chose not to enroll,” she explains. In addition, UCLA has three oversight committees for clinical research studies.

“It’s important that we help patients clearly understand the purpose of the trial



Nazy Zomorodian (left), RN, MSN, NP, CCRC, a urology nurse practitioner and director of the Clark Urological Center’s Clinical Trials Office, consults with Nancy Moldawer, RN, MSN, coordinator of the Kidney Cancer Program.

“We can’t always provide all of the answers, but we make sure our office is highly supportive, and that a nurse is available to consult with them any time they have questions or concerns.”

Nazy Zomorodian, RN, MSN, NP, CCRC

and why their physician recommends it for them, and respond to any questions or concerns they have,” says Nancy Moldawer, RN, MSN, coordinator of the Kidney Cancer Program. The two most common areas of inquiry, she says, are logistics and

side effects. Patients come to UCLA from all over the world to participate in clinical trials, and often the protocols require regular hospital visits and a lengthy stay near the facility. Regarding side effects, the nurses explain what patients in any previous trials have experienced. Although the nature of an experimental therapy is that there is some uncertainty, patients are assured of receiving a great deal of attention from the medical and nursing team.

“Patients want to know if this is going to make them sick,” says Ms Zomorodian. “We can’t always provide all of the answers, but we make sure our office is highly supportive, and that a nurse is available to consult with them any time they have questions or concerns about what is in their best interest. We tell them that they can stop in or call

any time, and that participation is always voluntary – they will receive the same high level of care regardless of whether they are in the clinical trial.”

Of course, patients also want to know the likelihood of whether the experimental treatment will help them. “For the most part, we don’t know the answer to that, and that’s a tough thing to tell patients,” says Ms Moldawer. “I can only tell them that this treatment was chosen because it showed promise.”

For many cancer patients who have not responded to conventional therapies, the clinical trial represents hope where there would otherwise be none. “We try not to give them unrealistic expectations,” says Ms Moldawer. “But there’s nothing wrong with being optimistic.”

FORMER PATIENT ENJOYS LIFE AFTER NEAR DEATH

Henry Meinhardt Was Told His Kidney Cancer Would Kill Him; Eight Years Later, He Recalls the UCLA Trial That Saved His Life

Each morning, Henry Meinhardt says a prayer for Drs Robert Figlin and Arie Belldegrun.

These are mornings the 69-year-old Mr Meinhardt never counted on seeing. February marked eight years since the business owner from Upper Marlboro, Md., came to UCLA to enroll in a clinical trial. He was suffering from advanced kidney disease and had been told by his physician in Maryland that his cancer was “too far gone” for surgery to help. “He said I would die on the operating table,” recalls Mr Meinhardt. “He sent me home and said there was nothing more that could be done.”

Mr Meinhardt traces the beginning of his ordeal to November 1994, when he first experienced severe back pain. He thought nothing of it until the next month, when a hacking cough came unaccompanied by any other cold symptoms. He was referred to a specialist, who diagnosed and treated him for lung cancer. By February 1995, when it was discovered that Mr Meinhardt’s primary tumor was in his kidney, he was urinating blood and could barely walk.

That was when friends of the Meinhardts in Tampa, Fla., happened to be watching a TV news program in which Dr Figlin was discussing an aggressive new immunotherapy regimen that the UCLA Kidney Cancer Program was offering in a clinical trial. They called Mr Meinhardt, who got the station to send a copy of the taped segment by overnight mail. “Within 10 days, I was being operated on at UCLA and was on my way to recovery,” Mr Meinhardt says.

Dr Belldegrun performed an extremely complicated and extensive surgery to remove Mr Meinhardt’s right kidney and the cancer that had already spread to other organs, including large veins and lymph nodes; Dr Figlin then treated him with an immunotherapy protocol designed to prime the patient’s immune system to recognize



Left to right: Dr Robert Figlin, Henry Meinhardt, Carrie Meinhardt, and Dr Arie Belldegrun. With his wife Carrie, Mr Meinhardt, who was cured by an experimental treatment given by the UCLA Kidney Cancer Program eight years ago, recently established a \$1 million endowment to support kidney cancer research at UCLA.

*“I had no reservations
[about participating
in the clinical trial].
This offered hope when
I had no hope. I would have
given everything I owned
for a chance to live.”*

Henry Meinhardt

and attack the remaining cancer cells in his body.

It was a trying experience – Mr Meinhardt lived at the Tiverton House across the street from UCLA Medical Center for almost a year, attending regular appointments. He had a catheter in his chest and a pump around his waist that infused interleukin-2 into his system. It wasn’t until a year after the surgery that he started to feel better. But he never regretted his decision to participate in the clinical trial. “I had no reservations,” he

says. “This offered hope when I had no hope. I would have given everything I owned for a chance to live.”

Today, the malignancies that had spread to Mr Meinhardt’s abdomen, lymphatic system and lungs show up only as tiny spots of scar tissue on scans and X-rays. He travels to UCLA once a year to be monitored for cancer, which has not returned since the treatment. Describing himself as “partially retired,” Mr Meinhardt maintains an active lifestyle – developing real estate, playing golf, sport fishing and spending time with his family. “I haven’t had any problems,” he says. “I truly feel I’ve been reborn.”

Recently, the Meinhardts established a \$1 million endowment to support kidney cancer research at UCLA. Dr Figlin was named the first holder of the Henry Alvin and Carrie L. Meinhardt Chair for Kidney Cancer Research. “They gave me life,” Mr Meinhardt says of the UCLA team. “I wanted to give back to them, so that they could help other patients.”

NEW FACULTY



Jamieson



Vilain



Zeng

The UCLA Department of Urology faculty welcomes three new members:

Christina A.M. Jamieson, PhD, brings expertise in functional genomics and molecular biology and immunology. Her research focuses on understanding how steroid hormones regulate cell death and survival in normal and cancerous cells. Dr Jamieson completed a post-doctoral fellowship in the laboratory of Dr Keith R. Yamamoto at UC San Francisco following her PhD work at Brandeis University.

Eric Vilain, MD, PhD, conducts research in molecular profiling of kidney cancer, cancer prevention, nutrition and cancer, gene and immune therapies, and molecular imaging. Dr Vilain received his medical degree from *Faculte de Medecine Necker Enfants Malades* in Paris, and his PhD at *Universite Pierre et Marie Curie/Pasteur Institute*.

Gang Zeng, PhD, earned his doctoral degree in biochemistry at Virginia Polytechnic Institute and State University in 1996 before completing a Cancer Research Training Award fellowship at the National Cancer Institute in 2000. His research interests include urologic oncology, tumor immunology, and cancer vaccine development.

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State-of-the-Art Urology Conference Draws Record Turnout

More than 300 urologists, from practices across the United States and Canada – and as far away as Belgium – attended the UCLA State-of-the-Art Urology Conference held February 13-16 at the Ritz-Carlton Hotel in Marina del Rey.

Dr William Aronson, associate professor of urology and chair of the annual conference, notes that the course provides practicing urologists with up-to-the-minute information and techniques for managing complex urological problems. Added this year was a special dry lab on ureteroscopy, directed by Dr Peter G. Schulam, head of the Department of Urology's Division of Endourology and Minimally Invasive Surgery; Drs Michael Phelan and Kent Perry, Dr Schulam's present and former fellows, respectively; and a visiting faculty member, Dr James E. Lingeman, director of research at Methodist Hospital Institute for Kidney Stone Disease and professor of urology at Indiana University School of Medicine.

Nine distinguished physicians joined Department of Urology faculty members as lecturers for the course: Drs David A. Ginsberg (University of Southern California), Steven A. Kaplan (Columbia University's College of Physicians and Surgeons), James E. Lingeman (Indiana University), James E. Montie (University of Michigan), John J. Mulcahy (Indiana University), Kenneth J. Pienta (University of Michigan), Mack Roach III (University of California, San Francisco), Peter T. Scardino (Memorial Sloan-Kettering Cancer Center), and George D. Webster (Duke University).

Over the four-day meeting, faculty covered all urologic sub-specialties: female urology, reconstructive surgery, neurogenic bladder, pediatric urology, management of renal stones, endourology, BPH, urologic oncology, impotence, and fertility. "The most vital aspect of the meeting is the interaction between participants and faculty," says Dr Aronson. "Panel discussions and case presentations end both the morning and afternoon sessions and are extremely popular with the attendees – as is the comprehensive course syllabus."

The Department of Urology has offered the State-of-the-Art Urology Conference in conjunction with the Office of Continuing Medical Education of the David Geffen School of Medicine at UCLA since 1985. The next conference is scheduled for March 12-14, 2004.

MINIMALLY INVASIVE SURGERY GOES SMALL(ER)

Pediatric Urology Patients Are Increasingly Benefiting from Surgical Approaches That Mean Less Pain and Trauma, Quicker Recovery



Dr Steven E. Lerman, assistant professor of urology, discusses an upcoming reconstructive surgery for 5-year-old Max Turtleaub with the patient and his parents, Rhea and Adam.

Minimally invasive surgery – in which specially trained practitioners, capitalizing on advances in optics, instrument design and imaging, poke needle-sized holes into patients and insert tiny instruments to do the work – is dramatically changing the operating room environment for adults. Now used in a growing number of urological procedures at major centers such as UCLA, the minimally invasive approach has resulted in less pain and trauma, quicker recovery, and equal or better outcomes compared with traditional “open” surgery.

For pediatric urologists, these results have raised the obvious question: Are the miniaturized instruments small enough to facilitate minimally invasive approaches in the smaller-sized patients they see? Increasingly, the answer is *yes*.

At UCLA’s Clark/Morrison Children’s Urological Center, minimally invasive approaches have been adopted for several indications, reports Steven E. Lerman, MD, assistant professor of urology. With assistance from Peter G. Schulam, MD, PhD, head of the department’s Division of Endourology and Minimally Invasive

Surgery, Dr Lerman has been successfully using laparoscopy – the most common minimally invasive surgery – primarily for three types of procedures:

Nephrectomy. When the kidney is congenitally malformed or scarred to the point that it is no longer functional and places the child at risk for infection, pain, and even hypertension, Dr Lerman can now, in many cases, remove the organ laparoscopically. While adults are more likely to undergo nephrectomies for cancer or transplantation, in children it is more apt to be for cases such as cystic disease of the kidney, severely malformed kidneys that are not functioning, and kidneys that have been scarred from infections to the point of lacking function. Rather than requiring a large incision, the procedure can be laparoscopically performed through 3-4 one-centimeter incisions. “Obviously, the older the child is, the more akin this is to an adult procedure,” says Dr Lerman. “But we keep lowering the age at which we can do laparoscopic nephrectomy, to the point where we’ve even done them in children as young as 5.”

Pyeloplasty. A second major advance

involves the laparoscopic approach to pyeloplasty, an operation to remove blockage in the ureter – the tube leading from the kidney to the bladder. Uretero-pelvic junction (UPJ) obstruction, usually caused by a congenital abnormality, prevents the easy flow of urine from the kidney into the bladder, and can lead to kidney malfunction. When the condition is diagnosed in infancy, it can usually be corrected through a small incision without the need for laparoscopy. But when diagnosed in older children, the laparoscopic technique can substantially reduce hospital stay and recovery time. “The fact that this is a reconstructive rather than a removal type of operation – we have to cut out the blocked segment and then sew the two good ends together inside the body – makes it more challenging to perform through a small incision,” Dr Lerman explains. But, drawing on the extensive experience of Dr Schulam, UCLA has been a leader in laparoscopic pyeloplasties for adolescents and children.

Undescended Testicle. In infants, laparoscopy is now increasingly used for the diagnosis and treatment of an undescended testicle. Testicles originally form in the male fetus’s abdomen, moving down the groin in the first two trimesters of pregnancy and descending to the scrotum in the final trimester. But approximately 3 percent of infants are born with a testicle remaining somewhere between the abdominal cavity and the scrotum. “In most of these children, the testicle is low enough that you can feel it, either in the groin or just above the scrotum,” Dr Lerman explains. But in a small percentage, the testicle is either not formed or lies undetected in the abdomen. Rather than making a large abdominal incision to determine if and where the testicle has formed, Dr Lerman can now typically make the diagnosis and take the appropriate course of action much less aggressively, by inserting a laparoscope in the belly button.

Dr Lerman is also involved in a national study, with UCLA as one of 12 participating sites, of the use of a new ther-

apy call Deflux to treat vesico-ureteral reflux (VUR) in children. VUR – the backflow of urine from the bladder toward the kidneys – makes children susceptible to urinary tract infections, and can potentially scar the kidney. When the reflux is low-grade, the typical approach is “observation” to see if the problem diminishes as the child matures; more than half of these cases will resolve on their own. For high-grade VUR or low-grade VUR that causes too many problems to warrant observation, the approach has been open surgery. Deflux provides a middle alternative – a gel is injected endoscopically into the bladder wall at the point where the ureters enter the bladder. Through a cystoscope, Dr Lerman can look into the bladder to see where the urine is refluxing toward the kidneys, then inject the gel to create a bulge that reduces the size of the openings of the ureters into the bladder as a way to elimi-



Dr Lerman has successfully used minimally invasive approaches for younger patients in a growing number of cases.

nate the backflow. “In Europe, studies show very good long-term results, with about 70 percent success in curing the reflux,” says Dr Lerman, “and so far the overwhelming consensus among parents of my patients has been that this is a wonderful option for those who don’t like the idea of observation, which requires that the child take an antibiotic every day as well as periodic x-ray tests – which require inserting a catheter into the bladder – to monitor the reflux.”

Dr Lerman believes minimally invasive approaches will continue to become more common as the surgical instrumentation improves to the point that results are the equivalent of open surgeries. “In pediatrics it’s going to lag a little bit behind the adults because of the size constraints,” he says, “but before long, we are likely to see these approaches become applicable to almost all cases.”



Jamieson



Singer



Han



Garraway



Bui

KUDOS

Christina Jamieson, PhD, assistant professor of urology and human genetics, was granted a \$20,000 Stein/Oppenheimer Award for her work in microarray technology and steroid receptors. The Stein/Oppenheimer Endowment Fund, established by Mr and Mrs Gerald H. Oppenheimer in 1990, provides seed money for worthwhile projects in health sciences at UCLA.

Jennifer Singer, MD, clinical instructor in renal transplantation, was named recipient of the 2002 Pfizer Scholar in Urology Award. The Department of Urology receives a \$2,000 grant in her name.

Dr Ken Han, oncology fellow, won third prize in the 2003 Clinical Prize Essay Contest for the American Urological Association.

Isla Garraway, MD, a fourth-year resident, has been named this year’s Esther and Abe M. Zarem Urology Research Fellow. Dr Garraway is spending her research year developing a mouse model for bladder cancer.

Dr Matthew H. T. Bui, a fifth-year resident, has garnered an array of prestigious awards: first prize in the Resident Essay competition, Los Angeles Urologic Society; second place in the American Urological Association’s Clinical Prize Essay Contest; and first place abstract for the Society of Urologic Oncology.

DONOR NEWS

Mrs Caroline W. Singleton presented Dr Jean deKernion, chair of the Department of Urology, with a \$1 million grant in honor of her late husband, Henry E. Singleton, one of the original members of the Department of Urology Advisory Board.

Stewart Resnick, a long-time supporter and member of the Department of Urology’s Advisory Board, and his wife Lynda were recently presented The UCLA Medal, the university’s highest honor, in recognition of their constant and generous support of the UCLA medical sciences.

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The Department of Urology welcomes your contributions throughout the year.

To send a contribution in support of our research programs or as a tribute or memorial, please make your check payable to "Regents of UC" and mail it to Ms Rain Burch at the Department of Urology, Box: 951738, Los Angeles, CA 90095-1738. For donations by credit card, please call Ms Burch at 310-794-2159.

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