THE CANCER LETTER

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Dear FDA: Provenge Provokes Letters From Opponents, Advocates, Investors

By Paul Goldberg

The controversy over the prostate cancer immunotherapy Provenge (sipuleucel-T) has touched off an explosion of letter writing to FDA, as scientists, physicians, patient advocates and investors take opposing sides on the agent's suitability for marketing.

The debates began two weeks ago, when Howard Scher, an oncologist at Memorial Sloan-Kettering Cancer Center who sat on the advisory panel that recommended approval for Provenge, wrote a letter urging the agency to uphold rigorous criteria for drug approval and turn down the prostate cancer vaccine (The Cancer Letter, April 13).

This week, the mailbag includes:

—A letter from Maha Hussain, chairman of the FDA Oncologic Drugs Advisory Committee, who, like Scher, took part in the March 29 meeting of the FDA Cellular, Tissue and Gene Therapies Advisory Committee as it recommended approval for Provenge. A copy of Hussain's letter was obtained by The Cancer Letter and is published below.

—A letter from Robert Erwin, president of the Marti Nelson Cancer

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FDA Should Delay Provenge Decision Pending Definitive Trial Results, ODAC Chairman Writes

By Paul Goldberg

Maha Hussain, the chairman of the FDA Oncologic Drugs Advisory Committee, urged the agency not to approve Provenge (sipuleucel-T) for prostate cancer, as recommended by another advisory committee.

"As physicians, we owe it to our patients to maintain the highest scientific standards and rigor," Hussain, a professor of medicine and urology at the University of Michigan, wrote in a letter dated April 23 and addressed to FDA Commissioner Andrew von Eschenbach and four other officials responsible for approval of oncology drugs.

"We owe them our objectivity and the assurance that when we make recommendations for treatment that we are basing our decisions on strong conclusive data," Hussain wrote. "We need your help to ensure maintaining this high standard."

Hussain, who sat on the Cellular, Tissue and Gene Therapies Advisory Committee during its March 29 consideration of Provenge, voted against approval.

Another prostate cancer expert who sat on that panel, Howard Scher,

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Critics Urge FDA To Turn Down Provenge Pending New Data

(Continued from page 1)

Foundation, a patient group that has been influential in advocating for scientific rigor and expanded access to cancer drugs. Concurring with Hussain and Scher, Erwin urges the agency to refer agents like Provenge to the ODAC, which has the expertise to evaluate them. The letter is posted at www.cancerletter.com.

—Taking exception, a group of doctors and scientists who met on investment websites prepared a point-by-point response to Scher's discussion of the Provenge application. A story about the group appears on page 4, and the group's letter is posted at www.cancerletter.com.

Provenge has an enthusiastic following among prostate cancer patients, who showed up en masse to speak at a public hearing and, literally, to cheer on committee members who spoke in support of the agent. A story about the patients' efforts to support the application appears on page 3.

If approved, Provenge would be indicated for men with asymptomatic metastatic androgen-independent prostate cancer. The Dendreon Corp. agent was brought before the Cellular, Tissue and Gene Therapies Advisory Committee even though two of the company's studies failed to demonstrate improvement in time to progression. However, an unplanned analysis of one of the studies found an improvement in survival.

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"We believe that the failure of two clinical trials to meet their primary endpoints should be an adequate reason for the FDA to demand additional data before approval is granted," patient advocate Erwin wrote in a letter to the agency. "Given the rigorous requirements the FDA normally establishes for both safety and efficacy data presented in support of a BLA or NDA, it is disappointing to us that the data submitted by Dendreon Corp. in support of its BLA for Sipuleucel-T were presented to an FDA Advisory Committee for review at all."

Erwin's letter states that the committee that recommended approval for Provenge lacked expertise in oncology.

"It is our view that ODAC members, because of their broader relevant clinical oncology experience, would have provided a better-informed assessment of what conclusions, if any, should validly be drawn about the clinical utility of this experimental vaccine," Erwin wrote. "Based on past experience, we believe that an ODAC review would have resulted in a negative vote on the question of efficacy, and that the sponsor would have obtained clear guidance on what would be needed in the future for an approval of their Biologic Licensing Application."

The agency has to make up its mind on Provenge before May 15.

"The FDA faces a difficult decision that, in my mind, clearly highlights the need to bring vaccine therapies and other biologics under the authority of the Office of Oncology Drug Products," said Richard Schilsky, former chairman of the Oncologic Drugs Advisory Committee, president-elect of the American Society of Clinical Oncology, and a dean at the University of Chicago.

"If FDA follows the advice of the advisory committee (comprised largely of non-oncologists) and approves Provenge, they will establish a precedent for approval of new drugs based on minimal evidence of effectiveness. This is a dangerous road to follow," Schilsky said. "If they reject the advice of their advisory committee, they will likely be criticized for doing so and for preventing patients from receiving a potentially beneficial therapy.

"Provenge is clearly a treatment that should be evaluated by medical reviewers in Office of Oncology Drug Products with the advice of ODAC, as its intended use is in cancer patients." Schilsky said. "The fact that it is a vaccine therapy is largely irrelevant to the issues of risk, benefit, and medical need for prostate cancer patients."

Patients "Raise A Voice" At FDA Advisory Committee

By Paul Goldberg

Talking with Wall Street analysts after his company's successful presentation before an FDA advisory committee March 29, Dendreon Corp. CEO Mitchell Gold listed the things that went right for Provenge.

"The comments of a lot of patients and patient advocacy groups were incredibly heartening, very compelling stories that I think really impacted a lot of people in the room, particularly me," Gold said.

Patients who showed up at the meeting of the Cellular, Tissue and Gene Therapies Advisory Committee wore dark-blue lanyards to show that they were, in fact, an organized contingent. Altogether, about 100 of these lanyards were given out that day, patient activists say. The night before the meeting, the patients met to coordinate their overall strategy, which included applauding whenever committee members spoke in favor of approval.

"There were a lot of people in that room who were having an epiphany that day," said Jan Manarite, one of the organizers of the patients' presentations. "We were hugging, crying. Even Dendreon told me they cried for hours. People were praying that day, and things were happening."

Manarite said the organizers of the patients' drive received no funding from Dendreon, and their budget, which she declined to disclose, was provided by Prostate Cancer Research Institute, a non-profit group. Some of these funds paid for Manarite's trip to Maryland from her home in Sanibel Island, Fla.

Before the meeting, Manarite's group, called Raise A Voice, proposed the following plan for action at the advisory committee meeting:

—"Raise A Voice would like to help coordinate a visual presence at this meeting. We will be passing out blue lanyards for everyone to wear. This will create something that the committee can easily see, as far as support of the prostate cancer community.

—"Raise A Voice would like to help prepare people who are interested in giving public comment between 11:30 am & 12:30 pm…

—"Raise A Voice would like to have a meeting in the hotel the night before (March 28th). Time and place to be announced.

—"Raise A Voice will be preparing to interact with committee members during all breaks. We still need someone to volunteer to research the different members of the committee."

The Raise A Voice documents are posted at http://www.prostate-cancer.org/advocacy/ProvengeFDAReview.html.

Manarite, whose husband is a prostate cancer survivor, said the effort grew out of communications between "a committee of people who have talked every month for about a year."

"What's beautiful about Raise A Voice is that we have people from all different organizations, including Us TOO, MaleCare, and the Virginia Prostate Cancer Coalition," Manarite said. "The National Prostate Cancer Coalition also was helpful. They were in the back scenes, but they were there. We talked, and they supported it, and they were amazed by what we were able to accomplish."

Manarite said her group's main message was that patients with advanced prostate cancer needed additional treatment options.

"The main goal is to try to fill a hole where men who have advanced prostate cancer and are running out of treatment options, right at the end of their rope, when they are wondering, 'Gee, how come there is a drug that has passed safety trials that we can't get to when it might be effective for us,'" Manarite said.

Manarite said Dendreon's public relations firm attempted to contact her, but she declined such overtures. "I didn't correspond with Dendreaon hardly at all before the meeting," she said. When the company's PR firm called, "I said, 'I am new at this, and I really think I need to not talk to you," she said. "I just feel intentional, and directed, and I am afraid that corresponding with you is going to somehow skew what we are trying to do. I also didn't talk much with investors, although I had one guy call, and I said, 'You are driven by money; I am driven by men with cancer, so I need to be really careful here.' I said, 'If you have something factual, send it to me.'

"I can put on blinders when I need to. I'll always be addressed with power, with money, with influence. All kinds of things are going to come across my desk, and if I can keep my blinders on, I am going to do the right thing."

Manarite said that the tactics of using small groups of advocates to approach members of the advisory committee during coffee breaks or as they moved about the premises, was developed in the AIDS movement. These groups are called "hit teams," Manarite said.

Though originally Raise A Voice planned to use such teams, the plan was ultimately abandoned. "I did interact with the people who gave comment," Manarite said. "We met together, we communicated, so these were

the people I sort of know about. As far as how many of them went up to committee members before or after, I am not sure."

Applause from the audience was appropriate, Manarite said.

"When do you applaud?" she said. "When something is interesting, and inspiring, and important?"

Ad Hoc Internet Group Sends Rebuttal To Scher's Letter

By Paul Goldberg

As biotech bloggers spread the word that oncologist Howard Scher wrote a letter urging FDA not to approve the Dendreon agent Provenge, a group of doctors and scientists formed a committee to produce a rebuttal.

These individuals represented a variety of specialties, and most of them weren't acquainted in the conventional sense of the word until they met on investor websites, where believers and detractors of biotech stocks gather to discuss hard news and conspiracy theories.

They were united by conviction that Scher's letter, published in April 13 issue of The Cancer Letter, merited a point-by-point response, said Kenneth McGuire, an aviation industry consultant and the only non-physician and non-scientist in the group.

"To get a disparate group of doctors and scientists together from across the country in a few days to respond to Dr. Scher's letter had to be done over the Internet," said McGuire, who acknowledges being a Dendreon shareholder.

Though he has no formal training in science or medicine, McGuire said he follows the immunology field closely. "I get a tremendous enjoyment out of doing research, especially in immunotherapies," he said to The Cancer Letter. "If I look around my office, I have a stack of perhaps 400 to 500 scientific studies in the field of immunotherapy."

McGuire described himself as a designated spokesman for the 15 authors, who supplied their real names and email addresses.

"These other guys and women are so damned busy, that if there was questions of some annotations, or format, or something like that, since I put a lot of that stuff in there, I would be in a better position to spend the time and review them with you than they would. Initially, I was not going to appear with regard to the letter, because I am not a physician nor a Ph.D. scientist," he said.

Dendreon wasn't involved in generating the document, McGuire said.

Echoing a hypothesis that has been expressed on biotech blogs, the group's 13-page letter doesn't take the authenticity of Scher's letter for granted.

"As a group of medical doctors and scientists we are writing to express our concern with the contents of a letter reportedly sent by Howard Scher, M.D. of the Memorial Sloan-Kettering Cancer Center, to the FDA," the letter states.

The Cancer Letter stands by the authenticity of Scher's letter.

The group then alleges that at the March 29 meeting, Scher voted in favor of approval of Provenge, "but changed his vote in an unclear manner." This is at odds with the record. Scher voted "Yes" on "reasonable" safety of the drug, and "No" on its efficacy. His rationale for casting these votes was stated at length throughout discussion, and in his letter, he hasn't challenged the manner in which his vote was recorded.

The group's letter states that FDA has established precedents it can invoke to approve Provenge. These would include the cardiology drug Coreg (carvedilol), sponsored by GlaxoSmithKline, and the lung cancer drug Alimta (pemetrexed), sponsored by Eli Lilly & Co.

"The FDA has allowed increases in overall survival to be statistically tested for significance where it was not a primary endpoint and has approved a supplementary NDA, where the primary endpoint of survival was not statistically significant," the letter states. In an interview, McGuire confirmed that this is a reference to Coreg.

The letter continues:

"The pre-specified primary endpoints in both the 9901 and the supporting 9902a trial were the time to disease progression (TTP). While not reaching statistical significance, a probability of 0.052 was undeniably close. It is understood that the positive Advisory Committee (AC) vote was primarily on the basis of the survival benefit subsequently discovered (and agreed by the FDA for the proper endpoint for filing of the Provenge BLA). The FDA has, in the past, considered an increase in overall survival in a life threatening disease, as a 'gold standard' worthy of its own 'alpha' of 0.05. See: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10027498&dopt=Abstract.

"In addition, the FDA has given Accelerated Approval to a supplementary NDA in NSCLC to Alimta, which failed to reach its primary endpoint of survival with a p value=0.93.: The Oncologist, Vol. 10, No. 6, 363-368, June 2005: FDA Drug Approval Summary:

Pemetrexed for Injection (Alimta) for the Treatment of Non-Small Cell Lung Cancer http://theoncologist.alphamedpress.org/cgi/content/full/10/6/363."

Experts in clinical trials contacted by The Cancer Letter disagree with this analysis. The Coreg example doesn't fit, said Colin Begg, chairman of the department of epidemiology and biostatistics at Memorial Sloan-Kettering Cancer Center.

"In exceptional circumstances, it makes sense to disregard the definitive FDA rule regarding the significance of the primary endpoint in two pivotal trials," Begg said. "But the caveat 'exceptional circumstances' is prominent in this discussion. In [Coreg] studies, there was overwhelming evidence (from several contemporaneous trials) of mortality benefit for the drug under investigation. One should regard this as a precedent only when the data (on the secondary endpoints) are exceptionally strong and consistent. It is my impression that this is far from the case regarding Provenge."

Susan Ellenberg, a professor of biostatistics at the University of Pennsylvania and a former FDA biostatistician, agrees.

"With Coreg, they had two studies, and in both studies survival was significantly improved," Ellenberg said. "So if one of the Coreg studies had shown a significant survival advantage, and the other one had shown nothing, maybe the FDA wouldn't have approved it." Also, in the case of Provenge, a survival advantage was found in an unplanned analysis of one of the two studies.

Almost reaching statistical significance isn't good enough, said Richard Schilsky, former chairman of ODAC, an incoming president-elect of the American Society of Clinical Oncology and an associate dean for clinical research at the University of Chicago.

"'Close' only applies in horseshoes, not drug approvals," Schilsky said. "The fact remains that two pivotal trials [of Provenge] failed to meet their primary endpoints, and only one of the two showed a modest survival advantage in a unplanned survival analysis."

The example of Alimta approval for non-small cell lung cancer doesn't apply either, experts say.

The reasons are fundamental. "Failure to reach significance is an attribute of success in a non-inferiority trial," Begg said. "So the purposes of the two studies are different, and the analogy is inappropriate."

James Symanowski, head of biostatistics at the Nevada Cancer Institute and a former Lilly biostatistician who was involved in clinical development of Alimta, agrees.

"They are citing the p-value for the test of superiority of pemetrexed over docetaxel," he said. "This was a non-inferiority trial, so, of course, the superiority p-value is large. The argument is making it appear that the FDA granted approval for Alimta even though the primary analysis had a pitiful p-value of 0.93. In fact, the pre-specified non-inferiority analysis was statistically significant. The FDA had problems with that analysis because the historical control used in the non-inferiority analysis was based on a trial that was too small (Sheppard, TAX317). Also, the pemetrexed-docetaxel trial was entirely internally consistent with all endpoints and subgroups, thereby providing convincing evidence that pemetrexed and docetaxel provided similar efficacy.

"Because the Provenge trials failed to show internal consistency, I don't believe it compares to the pem-docexatel trial; therefore, [Alimta] is not an appropriate precedent."

Also, Alimta received an accelerated approval rather than a regular approval, Schilsky noted.

"Although Alimta failed to demonstrate superiority in survival to docetaxel, an active control with a known survival benefit compared to best supportive care, the drug was approved under the accelerated approval mechanism based on secondary endpoints considered reasonably likely to predict clinical benefit along with a more favorable safety profile than the established therapy," Schilsky said.

Hussain: ODAC Should Review Cancer Immunotherapies

(Continued from page 1)

of Memorial Sloan Kettering Cancer Center, wrote a similar letter to the agency.

In her letter, Hussain urged the agency to refrain from approving the agent until its sponsor, Dendreon Corp., completes a clinical trial that would "lead to definitive answers as to the true efficacy and safety of this agent."

Ultimately, the Provenge application should go to ODAC, since that committee has "the proper expertise in the context at hand," Hussain wrote.

The text of Hussain's letter appears below:

It is with concern and professional obligation that I write to you as a member of the FDA's Advisory Committee that recently reviewed Sipuleucel-T on March 29, 2007. My concerns relate to medical, scientific and procedural aspects of the meeting and the precedence that will be set for future reviews.

By way of introduction, I am an academic medical

oncologist with expertise in GU oncology, extensive clinical trials experience and have been the PI of several NCI sponsored multi-center trials including randomized phase II and III trials. Currently, I am the PI of a Prostate Cancer Clinical Trials grant funded by the Department of Defense that focuses on phase I and II trials in prostate cancer. My experience also includes co-chairing the prostate cancer subcommittee of SWOG overseeing development of national trials for advanced prostate cancer for the past 13 years. I have served as an ad hoc FDA consultant for several years and currently serve as a member of the Oncology Drugs Advisory Committee. I was a member of and chaired the ODAC special session on prostate cancer endpoints, March 3, 2005, and have been actively involved in the development of endpoints for this disease, a summary of which was recently presented at the 2007 Prostate Cancer ASCO meeting.

I was one of the four members who voted "No" to whether the submitted data on Sipuleucel-T established "efficacy" or "demonstrated substantial evidence of benefit" in the intended population at the recent advisory committee meeting.

From the medical and scientific aspects the recommendations for approval that may be inferred from the vote are based on data that can only be characterized at best as "suggestive" of possible benefit. As the discussant for Q5 regarding the persuasiveness of the efficacy evidence my comments are public record but to summarize my conclusion was that the data presented is not conclusive. The context here is not *"is the treatment promising"* or *"does it open the door for more immunotherapy research,"* the context here is "is the treatment effective and are the results solid" such that this therapy should be offered as *"The Standard of Care"* by physicians to thousands of patients with the confidence that their recommendations truly serves the best interest of the patients. First of all the lead trial (study 1) was a small trial by any standard with 127 patients in total of whom only 82 were treated with Sipuleucel-T. The study was not powered for survival nor was survival an end point. A post hoc analysis indicated a significant survival difference but there were no significant differences between the Sipuleucel-T and placebo group with regard to any of the disease manifestations including PSA, time to disease progression (primary endpoint) or pain. This coupled with a clear imbalance in the arms with the control arm having more patients with bone and soft tissue disease thus potentially bulkier disease, more patients with higher Gleason scores, more % with prior chemotherapy and questions regarding the nature of the agent administered as the control (please see comments below), the small sample size, the fact that survival was not powered for and is a post hoc analysis could lead to a plausible conclusion that the observed survival difference may be related to other factors or chance alone and not to the treatment effect. Please contrast this data with the two phase III trials (TAX-327 with 997 patients, SWOG -9916 with 770 patients) that led to the approval of docetaxel. Both of these trials had very consistent results across them and conclusively demonstrated a survival advantage with notable effects on other disease manifestations.

The sponsor presented a second "supportive trial" which was also a small prematurely terminated trial which showed about a 3 month difference in survival which was not statistically significant. The trial results were especially problematic since both arms had a poorer survival (15.7 and 19.0 months) than expected for asymptomatic patients and worse than the survival observed in study 1. This occurred despite similar eligibility criteria to study 1. Furthermore, even the best arm "Sipuleucel-T treated patients" had a median survival of (19 months) which is comparable to the "asymptomatic" subgroup of men treated on the mitoxantrone arm of the Tax327 trial (19.8 months, Berhold et al, ASCO Prostate Cancer Symposium 2007). Please note that mitoxantrone is not considered the standard first line therapy in general or for asymptomatic patients.

This clearly raises concern regarding the true efficacy of the agent and reproducibility and reliability of the data hence the application in the intended population at large. Furthermore, considering that the "placebo" treated patients had an unexpected poor survival of 15.7 months, which is worse than the median survival of patients on mitoxantrone arm of the TAX-327 of 16.4 months (NEJM 04) which also included symptomatic patients, raising questions regarding a negative effect from the placebo thus leading to an apparent survival benefit. Issues regarding CVAs, particularly in the intended population, are also of concern without mature toxicity data and in the context of inconclusive efficacy data.

As you know, a definitive trial is in progress and is within 100 patients of achieving target accrual. This trial will lead to definitive answers as to the true efficacy and safety of this agent. These questions will never be answered if the decision regarding this agent is not deferred at this time until all patients are accrued and data are mature, for obvious reasons.

From the scientific and procedural aspects, in general, it would seem that at the end of the day what should determine a positive verdict in any therapeutic trial is the strength of the evidence as critically reviewed by an Advisory Committee with the proper expertise in the context at hand (ODAC in the case of a therapeutic cancer trial), with clear guidance on the questions posed to the committee within the framework of the regulatory guidelines and requirements of the FDA for approval. This needs to be coupled with an atmosphere that is conducive to an objective discussion and vote.

Another concern, based on this case, is the appearance of discordance in the burden of proof required for regulatory approval between CBER and CDER. In the meeting regarding endpoints in 2005, ODAC reaffirmed the importance of powering trials for endpoints that measure true clinical benefit. But fundamentally here this particular agent did not even meet criteria for its primary endpoint.

In conclusion, as physicians we owe it to our patients to maintain the highest scientific standards and rigor. We owe them our objectivity and the assurance that when we make recommendations for treatment that we are basing our decisions on strong conclusive data. We need your help to ensure maintaining this high standard.

In the Cancer Centers:

Roswell Park, Cedars-Sinai, Purdue, Name New Directors

By Kirsten Boyd Goldberg

Three cancer centers announced new directors in the past week. They are **Donald Trump** at Roswell Park Cancer Institute, **Steven Piantadosi** at the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center, and **Timothy Ratliff** at the Purdue Cancer Center at University of Iowa.

At Roswell Park, President and CEO **David Hohn** has been working with Trump since 2002 with the plan that Trump would one day become his successor. Trump served as senior vice president for clinical research and chairman of the Department of Medicine, and was named associate director in 2006.

Hohn stepped down March 31 to become executive director of health policy and president emeritus. The Board of Directors officially introduced Trump as the new president and CEO on April 24.

"Dr. Trump has the skills, experience, leadership and stature to advance further the growth and development of Roswell Park to national and international prominence as a leader in cancer research, treatment, prevention and education," said **David Zebro**, board chairman.

Trump's research in prostate cancer demonstrated the antitumor mechanisms and therapeutic effects of high dose vitamin D, which is being evaluated in a phase III trial. He holds patents and has two pending for his vitamin D work. Trump authored or co-authored more than 200 peer-review scientific papers. He is a member of NIH and Department of Defense peer review committees and an advisor to many cancer centers.

"Dr. Trump's service as a medical oncologist, an innovative researcher, and respected leader has given him a distinguished reputation and makes him uniquely qualified for his new role," said **Richard Daines**, New York State Commissioner of Health. "Dr. Trump will provide imaginative and strategic leadership at Roswell Park for years to come."

In the past 10 years of Hohn's presidency, RPCI has transitioned from being a component of the New York State Department of Health to becoming a public benefit corporation. While the center still receives state funding, it has been able to renovate or build buildings, open an endowment fund, and enter into contracts without state involvement, acting as a freestanding cancer center. The center recruited 165 faculty in the past eight years, and grant funding has tripled to $80 million. The operating budget increased from $180 million 10 years ago to $480 million this fiscal year.

"Roswell Park has grown considerably in the last 10 years, and my intent is to continue the upward trajectory of growth," Trump said to The Cancer Letter. "We are particularly focused on the recruitment of high-quality faculty."

Trump said his priorities are to expand the center's expertise in cancer imaging and biotechnology. "We, like many places, have a nascent program in cancer imaging, with excellent preclinical work and excellent clinical service capability, but we will target the recruitment of an excellent imager to bring the preclinical and clinical areas together," Trump said.

In the past six months, the center has spun off three biotech companies. Trump hopes to continue that trend and enhance RPCI's role as a economic development force for western New York.

"Our partnership with the state has been invigorated and we are positioned for great things," Trump said. "We need to get better. We are well known and have a long history in cancer research. But we have the opportunity to become one of the very best in the country. That's my goal over the next 10 years to lead us in that direction."

Prior to joining RPCI, Trump was deputy director

for clinical investigation at the University of Pittsburgh Cancer Institute. He earned his M.D. from Johns Hopkins University School of Medicine in 1970. From 1970 to 1975, he completed an internship and residency training in Medicine and a fellowship in Oncology and served as Chief Resident in Internal Medicine at The Johns Hopkins Hospital.

* * *

Piantadosi, professor of oncology at Johns Hopkins University School of Medicine and director of biostatistics at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, was named the first director of the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai on April 19.

Piantadosi is an expert in cancer clinical trial design, and has been a member of several FDA committees. He has also served on external advisory boards for other cancer centers, including the M.D. Anderson Comprehensive Cancer Center and the Yale Comprehensive Cancer Center. He is the author of the textbook "Clinical Trials: A Methodologic Perspective."

Piantadosi is a senior editor of the journal Clinical Cancer Research, and holds leadership positions in several multi-center clinical trials, including vice-chairman for the National Emphysema Treatment Trial.

"One of the things that attracted me to Cedars-Sinai is its national reputation for high-quality patient care and its strengths in translational research, bringing the latest research from the laboratory to the patient's bedside quickly," Piantadosi said. "Cedars-Sinai is a unique institution among American academic medical centers, and I am deeply honored and excited by this opportunity."

Piantadosi earned his M.D. from the University of North Carolina and Ph.D. in biomathematics from the University of Alabama at Birmingham.

"Innovative cancer research with a focus on getting treatments to our patients has been a primary strength at Cedars-Sinai for many years, and Dr. Piantadosi's international leadership in cancer research and patient care is a perfect match for our Samuel Oschin Comprehensive Cancer Institute," said **Thomas Priselac**, Cedars-Sinai president and CEO.

"Dr. Piantadosi's appointment as director is an important milestone for the Samuel Oschin Comprehensive Cancer Institute, and signals the start of a new phase of development for our excellent cancer research and patient-care programs," said **Shlomo Melmed**, Cedars-Sinai's senior vice president for academic affairs and chief academic officer. "His international stature and leadership skills will be a huge asset to Cedars-Sinai and cancer patients everywhere."

* * *

Ratliff will begin his appointment as director of the Purdue Cancer Center on July 1. He also will have an appointment as professor of comparative pathobiology in the School of Veterinary Medicine.

Ratliff has been the Andersen-Hebbeln Professor of Prostate Cancer Research at the University of Iowa College of Medicine for the past 10 years and has served as research vice chairman for the Department of Urology for the past six years.

"Professor Ratliff is nationally recognized for his achievements in urologic research and will continue Purdue's history of innovation in pursuit of the goal set by the National Institutes of Health to eliminate cancer as a cause of suffering and death," said **Charles Rutledge**, vice president for research. "He understands the importance of multidisciplinary collaboration and will build upon Purdue's strengths in engineering and science and the resources offered by Discovery Park. Professor Ratliff's leadership will support the center's accomplishments and enable future successes."

Richard Borch served as director of the cancer center for the past nine years and will continue as head of the department of medicinal chemistry and molecular pharmacology in Purdue's College of Pharmacy, Nursing and Health Sciences.

"The Purdue Cancer Center is one of the best basic-research centers in the world," Ratliff said. "It fosters a remarkable collaboration across departments and across the nation that is key to success in the fight against cancer."

Ratliff is a member of the American Urological Association and is founder of the Society for Basic Urologic Research.

His research has focused on immunotherapy studies using prostate and bladder cancer models to address questions regarding activation of antitumor responses, characterization of antitumor effector mechanisms and the regulation of antitumor immunity.

Ratliff received his bachelor's degree in biology and chemistry from the University of Texas, Arlington. He received his master's degree in biology at Texas A&M, Commerce, and his doctorate in microbiology at the University of Arkansas.

Prior to joining the faculty of University of Iowa, he was a faculty member of Washington University School of Medicine.

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