

THE

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Cancer Centers: Permanent Reinvention

DePinho Apologizes For Investment Advice: On CNBC He Recommended A Firm He Founded

By Paul Goldberg

A recent television appearance by MD Anderson Cancer Center President Ronald DePinho raises questions about the compatibility of his multiple roles. He is at once, a state employee, a scientist and a major shareholder in a publically traded company.

Appearing on the CNBC program “Closing Bell with Maria Bartiromo” on May 18, DePinho was introduced as president of MD Anderson and was asked to provide investment advice based on data that would be presented at the upcoming annual meeting of the American Society of Clinical Oncology.

Thus prompted, DePinho proceeded to extol the virtues of AVEO Pharmaceuticals, a company he co-founded.

DePinho’s investment advice to CNBC viewers marks the second cluster of conflicts of interest to emerge during his presidency. Recently, top-level scientists objected to the decision by Texas officials to award a one-year \$18-million grant to a technology “incubator” co-directed by DePinho’s wife, Lynda Chin, a scientist at his institution.

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DePinho Seeks New Review of Incubator Proposal

By Paul Goldberg

Facing a torrent of adverse coverage in the media, MD Anderson President Ronald DePinho asked state officials to conduct another level of review of his institution’s proposal for a biotechnology incubator.

The request is remarkable because the \$20 million proposal was recently approved for funding—and DePinho’s request represents at least an appearance of backing down.

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In Brief

City of Hope Awarded \$5.2 Million Grant For Glioma Immunotherapy Research

CITY OF HOPE received a \$5.2 million grant for early translational research from the **California Institute for Regenerative Medicine**. The grant will support the development of a T-cell-based immunotherapy against glioma stem cells.

“In this research, we are genetically engineering a central memory T cell that targets proteins expressed by glioma stem cells,” said Stephen Forman, the

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DePinho's Stock Tip Illustrates UT's Inability to Manage His Conflicts

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The proposal didn't go through regular channels of review, either at MD Anderson or at the state agency (The Cancer Letter, May 25).

Responding to questions about his CNBC appearance, DePinho said that he had made a "mistake" by giving investment advice and discussing his role in AVEO.

"I am a public official in a position of trust, and I should never comment on any of my personal holdings or give investment advice," he said to The Cancer Letter. "It was a mistake for me to do so on the CNBC interview."

DePinho blamed the medium.

"It was live TV," he said. "It was a very fast-moving interview, which in the context of what Maria and I were talking beforehand, versus what we were talking on air, etc. It unfolded the way it did. And it will not happen again."

Apologies notwithstanding, the episode illustrates failure on the part of the University of Texas System to manage DePinho's conflicts. Analysis of this new cluster of conflicts has to start with AVEO.

The company's stock may indeed be a good pick for some investors, though probably not for widows and orphans. AVEO is developing a drug called tivozanib, a tyrosine kinase inhibitor. If approved—and renal cancer experts say that approval is not a sure thing—tivozanib

would become drug No. 8 and the fifth drug in its class for the treatment of this relatively rare disease.

According to federal filings, DePinho and his family trust hold 590,440 shares in AVEO. For three days preceding DePinho's appearance on CNBC, AVEO's stock price had been in a free-fall, trading at \$11.28 per share just before DePinho went on camera.

The slide of per-share price, on a heavy trading volume, coincided with the announcement of top-line results from the company-sponsored clinical trial, which investors apparently interpreted as underwhelming.

However, following DePinho's appearance, the share price started to climb back up, trading at about \$12.73 when the market closed on May 31, making the DePinho holdings worth about \$7.5 million.

While there is no way to attribute this bump in the price of AVEO's stock to DePinho's on-camera salesmanship, the video clip provides a remarkable opportunity to watch him juggle his multiple roles and business interests.

Introduced as MD Anderson president, DePinho says that investors should be careful and bet only on companies that are guided by emerging molecular-level insight into cancer.

DePinho's briefly mentions Genentech as an example of such a company, then segues to AVEO.

"A company that I was involved in founding—AVEO Pharmaceuticals, one of the most successful biotech," DePinho said, is developing "a very effective drug that has a superior safety profile for renal cell cancer, a major unmet need."

After recommending his company's stock, DePinho returns to his MD Anderson role, discussing his vision of the cancer equivalent of the "moon shot," which involves his institution spearheading an effort to cure five cancers in five years (The Cancer Letter, May 25).

A video of DePinho's appearance is posted at <http://video.cnb.com/gallery/?video=3000091289&play=1>, and a full transcript is published at <http://www.cancerletter.com/categories/documents>.

An excerpt from the transcript follows:

MARIA BARTIROMO: *Are there companies out there, from an investment standpoint; for our audiences are obviously looking for money-making opportunities, trying to figure out how to capitalize on what's going on in this marriage of health care and technology and biotech. Are there companies out there that you think are most promising, and also what is going to come out of this ASCO meeting, you think?*

RONALD DePINHO: Well, the companies in the

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biotech sector, you have to be very careful because you have to really understand which companies are driven by good management, that are driven by the kinds of scientific advances that I've mentioned, and there are a few of them out there. Historically of course Genentech was one of the prime examples of this, more recently a company...

MB: *They were the first to come out with that "targeted..."*

RD: Right. Targeted. So you think about Herceptin and so on, those are very important advances. And, in fact, some of the most effective drugs have come out of the idea of using science to shepherd the cancer drug development.

A company that I was involved in founding—AVEO Pharmaceuticals, one of the more successful biotechs...

MB: *That's A-V-E-O...*

RD: That's correct... Has utilized, has exploited science-driven drug discovery, and it's about to announce, or has announced already publicly, and will present in detail at ASCO, a very effective drug that has a superior safety profile for renal cell cancer, a major unmet need.

So these are massive advances in our ability to really do something about a disease that has long been very refractory.

The Changing of the Hats

Experts in medical ethics said to The Cancer Letter that they are troubled by this juggling act.

"This kind of media appearances are highly morally suspect, because you are conflating a number of different roles that have to be kept separate," said Arthur Caplan, director of the Division of Medical Ethics in the Department of Population Health at the NYU Langone Medical Center. "These include the role of a cancer researcher, the role as president of MD Anderson, the role as owner-investor in a company. This creates mixing of roles back-and-forth that cannot be mixed if you are to perform each of them in a responsible manner.

"Taking advantage of a platform to tout your company and its drugs means that you have to stay in that role and not move back and forth to other positions," Caplan said.

Several MD Anderson insiders said that, DePinho's apology aside, they were shocked to see their institution's new leader blatantly advance his own interests.

MD Anderson veterans note that DePinho's predecessor, John Mendelsohn, had developed the drug Erbitux, for which he was amply compensated with

ImClone stock.

However, Mendelsohn never acted as a pitchman for the drug developer, ImClone Inc. MD Anderson's investigators continued to work with other EGFR receptors, including Iressa and Tarceva, and after The Washington Post noted that MD Anderson was putting patients on Erbitux studies, the institution created a level of review to make certain that these studies were ethical.

Experts in renal cancer say that DePinho's characterization of the AVEO drug as meeting a "major unmet need" is debatable.

For one thing, the phrase echoes the term of trade "unmet medical need," which describes the FDA criteria for awarding a "Fast Track" designation, which allows the agency to work closer with the sponsor to get an important drug on the market. AVEO officials said to The Cancer Letter that they aren't applying for the designation.

With eight drugs on the market, the renal cancer indication has more treatment options than most cancers.

In the pivotal trial, AVEO's tivozanib beat an older-generation TKI, sorafenib, which is all that can be said. Alas, tivozanib efficacy data—a delay in progression—had triggered a selloff.

When it comes to renal cell carcinoma FDA approval criteria are fairly explicit. Still, it's not at all certain whether the drug would meet the bar, experts say.

If the drug is approved, the upside may not be dramatic. As the drug would be the ninth therapy and the fifth tyrosine kinase inhibitor used to treat a relatively rare cancer, it will never ring up the sales of a big-indication drug like Avastin.

Since AVEO has no ready-to-go No. 2 product in phase III trials, the company's future would be uncertain.

Questions arising from such a close relationship between a cancer center and a company can reach deep. For example, MD Anderson recently took part in a multi-institutional phase I study of an AVEO compound and exploratory biomarkers in patients with advanced solid tumors: <http://www.aveooncology.com/wp-content/uploads/2012/05/AVEO-AV-203-Ph1-Initiation-PR-Final-52312.pdf>

Can conflicts of interest at the top of the institution creep into this and other studies involving AVEO compounds? This could be particularly sensitive in a phase I study, which is conducted with no therapeutic intent, ethics experts say.

DePinho said he didn't have first-hand knowledge of how the phase I study of an AVEO compound was scrutinized.

“This is something that is very heavily managed in academic institutions,” he said. “These are things that are very stringently examined at the level of systems and at the level of compliance, and these are things that have been examined in great detail with tremendous transparency.”

DePinho declined to answer further questions.

“At a time when the US Public Health Service and major medical journals are ratcheting up conflict of interest guidelines, it is morally unconscionable that the head of a leading public medical center should have an equity interest in a company whose financial interests can be affected by research at the center,” said Sheldon Krinsky, professor of Urban and Environmental Policy and Planning at Tufts University and author of a book on conflicts of interest in medicine, “Science in the Private Interest.”

“A director donning two hats will always give the appearance of having a conflict of interest,” Krinsky said.

Murky Road to CNBC

How did DePinho get on CNBC? What role did any of the parties involved in management of conflicts of interest play in arranging the appearance?

“AVEO had nothing to do with Dr. DePinho getting booked on CNBC,” said Rob Kloppenburg, the AVEO vice president of corporate communications. “We think the best thing to do would be to discuss the impetus for the interview with his representatives at MD Anderson.”

MD Anderson officials said the interview was arranged through their office, but didn’t respond to a series of questions from The Cancer Letter.

The institution’s officials have no authority over managing DePinho’s conflicts.

Last week, in an interview with The Cancer Letter, MD Anderson Provost Raymond DuBois said DePinho’s and Chin’s conflicts are managed by the University of Texas Board of Regents.

“There was recognition by the University of Texas System and the executive vice chancellor, [Kenneth] Shine, when Lynda came on board of the potential conflicts of interest when you have a department chair in the institution and her husband as the president,” DuBois said. “You always worry about potential conflicts of interest, but we’ve tried to put things in place to alleviate those conflicts.

“And Lynda actually reports directly to Dr. Ken Shine. She doesn’t report to Ron or to me—it’s set up so that she reports to Dr. Shine. Obviously Dr. Shine and I confer on things and make sure that we are all on

the same page. But that reporting relationship was set up from the very beginning when Ron and Lynda came on board.”

Officials from the UT System didn’t respond to questions from The Cancer Letter about DePinho’s CNBC appearance.

FDA Approval Standards in RCC

AVEO officials say they plan to file a New Drug Application with FDA late this year. The company is developing the drug in partnership with Astellas Pharma Inc. of Tokyo.

The agency described its approval standards for renal cell carcinoma late last year, during the FDA Oncologic Drugs Advisory Committee discussion of the Pfizer drug Inlyta (axitinib), an oral vascular endothelial growth factor inhibitor for advanced renal cell carcinoma after failure of a first-line systemic therapy (The Cancer Letter, Dec. 16, 2011).

The Pfizer drug was tested against sorafenib, as is tivozanib. Sorafenib is a first-generation TKI.

Experts say that the tivozanib’s approvability would likely hinge on the question of whether the control—sorafenib—is active and whether the comparison adds benefits or decreases toxicity.

Usually, approvals based on delay in disease progression are based on FDA’s and ODAC’s opinions of whether such delay is clinically significant.

“If you add a drug to an active control, you always have more toxicity and therefore you are completely dependent on demonstrating sufficient added benefit to make up for the added risk,” one leading expert in the field said in an interview. “If you are comparing to an active control, you just have to demonstrate that you are doing no worse in regards to efficacy and no worse in regards to toxicity.

“The issue then becomes whether the control is appropriate.”

AVEO’s trial compared its drug to an active control, which means that a benefit can be argued if:

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1) The active control is considered to be an appropriate treatment. The control treatment is “appropriate” but one can argue whether it is “the most appropriate.” After this, the drug has to meet the following conditions:

2) If the magnitude of benefit in progression-free survival is thought to be “clinically significant”—also a debatable contention, OR

3) The probability of investigational therapy being worse than active control is low (true) AND toxicity is no worse (probably true)

“The issue here is the control and whether the FDA should punish a company that has a drug that is not first to market,” the expert said. “We have to remember that the FDA’s mandate is ‘safe and effective,’ not ‘better than what we have.’”

The AVEO data will be presented June 2 at an ASCO oral session. The results will be presented by Robert Motzer, attending physician, genitourinary oncology service, Memorial Sloan-Kettering Cancer Center.

The study, called TIVO-1, is the first superiority pivotal study in first-line advanced renal cell carcinoma in which tivozanib demonstrated statistically significant and clinically meaningful PFS superiority versus sorafenib in advanced RCC, the company said.

“TIVO-1 is novel in that this phase III clinical study used an approved targeted comparator drug to evaluate first-line RCC treatment,” Motzer said in a statement. “Patients in the study who had no prior treatment for advanced kidney cancer and who were given tivozanib met the primary PFS endpoint and tolerated the drug well.”

A total of 517 patients were randomized to tivozanib (n=260) or sorafenib (n=257). The performance status and other prognostic indicators of patients enrolled in this study were consistent with other pivotal trials in first-line advanced RCC.

Key data from TIVO-1 to be highlighted include (Abstract # 4501):

Based on independent radiological reviews, tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib in the overall (Intent To Treat) study population (HR=0.797, 95% CI 0.639–0.993; P=0.042). Objective response rate for tivozanib was 33 percent compared to 23 percent for sorafenib (p=0.014). The efficacy advantage of tivozanib over sorafenib was consistent across subgroups in the study.

In patients who were treatment-naïve for advanced

RCC (70 percent of total study population), tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for sorafenib (HR 0.756, 95% CI 0.580–0.985; P=0.037). This is the longest median PFS reported to date in treatment-naïve advanced RCC patients in a pivotal study.

In the subpopulation of patients who were pretreated with systemic therapy including cytokines (30 percent of total study population), tivozanib demonstrated an improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib.

Study results demonstrated favorable tolerability as evidenced by a distinctively low rate of dose interruptions and reductions. The most common adverse event (all grades/≥grade 3) for tivozanib was hypertension (T: 44%/25% vs S: 34%/17%) and for sorafenib was hand-foot syndrome (T: 13%/2% vs S: 54%/17%). Other adverse events included diarrhea (T: 22%/2% vs S: 32%/6%), fatigue (T: 18%/5% vs S: 16%/4%), and neutropenia (T: 10%/2% vs S: 9%/2%).

The rate of dose interruptions due to adverse events was 18 percent for tivozanib compared to 35 percent for sorafenib (p<0.001).

The rate of dose reductions was 14 percent for tivozanib compared to 44 percent for sorafenib (p<0.001).

Overall survival data are not yet mature, the company said.

In TIVO-1, 53 percent of patients randomized to the sorafenib arm of the trial went on to receive subsequent therapy, nearly all of whom received tivozanib after sorafenib.

Based on an early interim analysis, 81 percent of these patients achieved one-year overall survival.

In comparison, only 17 percent of patients randomized to tivozanib went on to receive a subsequent therapy, and 77 percent of these patients achieved one-year overall survival.

Mature data are expected to be presented in 2013, the company said.

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DePinho: Incubator Plan Will Not Get Provost's Review

(Continued from page 1)

In a letter to officials of the Cancer Prevention & Research Institute of Texas, DePinho asked for a re-review of the project that would give \$18 million this year to a project where his wife, Lynda Chin, a scientist at MD Anderson, serves as the principal investigator.

The move is unlikely to quell the opposition from top-level scientists who review grant proposals for the \$3 billion, tax-funded CPRIT. In a letter to CPRIT, these reviewers said that the MD Anderson proposal is based on scientific research and therefore should be reviewed as a scientific project rather than a commercialization project.

Alfred Gilman, a Nobel laureate who serves as CPRIT's chief scientific officer, resigned over the award to MD Anderson. A group of his colleagues—including Phillip Sharp, of the Massachusetts Institute of Technology Koch Institute for Integrative Cancer Research—said that they, too, may resign.

Critics say that funding the incubator was even more inappropriate, because CPRIT chose not to fund \$40-million-worth of research grants.

Last week, The Cancer Letter documented how standard procedures weren't followed in review and submission of the proposal both at MD Anderson and at CPRIT (The Cancer Letter, May 25; <http://www.cancerletter.com/articles/20120525>). Separately, the Houston Chronicle documented conflicts of interest on the part of members of the CPRIT commercialization panel that reviewed the six-and-a-half-page proposal from MD Anderson.

Though DePinho asked for a re-review, it appears that he and CPRIT officials envision refining the bureaucratic machinery and better managing the conflicts on the part of members of the commercialization panel while stopping short of addressing the fundamental problem.

In his letter, DePinho refers to “inaccurate allegations that appear in some of the published reports on the CPRIT incubator infrastructure awards,” yet he addresses the lack of adherence to standard procedure for submission of grants by MD Anderson researchers.

“These commercialization incubator awards are uncharted territory for all of us, and there are lessons to be learned from the process,” DePinho writes. “For example, at MD Anderson, these business plans should not be reviewed by the Provost's office, but by Business Affairs, and we are instituting that process.”

The text of DePinho's May 30 letter to CPRIT Executive Director Bill Gimson follows:

Dear Bill,

I know you share my concern with the inaccurate allegations that appear in some of the published reports on the CPRIT incubator infrastructure awards. Both CPRIT, which has a deserved reputation of integrity and rigorous, unbiased reviews, and MD Anderson, which values our equally deserved reputation of exemplary faculty and incredible track record in awards, are understandably dismayed by these false allegations. It is also understandable why my scientific colleagues would be concerned, in the absence of all of the facts, on how we got to the present situation. At this point, both institutions have critical work to conduct and must do everything possible to move beyond this controversy and reassure the public of this award's value to future cancer patients.

We were gratified that CPRIT came to us because they recognized the transformational nature of MD Anderson's Institute for Applied Cancer Science (IACS), and its collaborations with Rice University. These commercialization incubator awards are uncharted territory for all of us, and there are lessons to be learned from the process. For example, at MD Anderson, these business plans should not be reviewed by the Provost's office, but by Business Affairs, and we are instituting that process.

We appreciate CPRIT's time and help in answering questions that ensured we submitted the best proposal possible following CPRIT's processes. We also were made aware that we should expect to proceed to post-award review and contracting between CPRIT and MD Anderson if the award was granted. While CPRIT designated Dr. Lynda Chin as the PI, it should be noted that Dr. Giulio Draetta is the IACS director and he and the entire IACS leadership team prepared the business plan in response to CPRIT's request for application.

We are absolutely convinced that our proposal is strong, commercially viable and would stand up to additional review. Thus, we would be pleased to resubmit the proposal to CPRIT for any further review that it deems appropriate

Additionally, we are sufficiently confident of the demonstrable benefits of the proposal that we would be willing to agree to have the award funds placed in an escrow account for one year, and let the results we anticipate be judged before our receipt of the award.

These are just proposals for you to consider, but we are open to any thoughts you may have to validate MD Anderson's submission and the work of CPRIT. Please don't hesitate to contact me directly.

The text of Gimson's response, also dated May 30, appears below:

Dear Ron:

Thank you for your letter today. We at CPRIT have a legal obligation—and moral imperative—to make investments that have the potential for breakthroughs in the prevention and cure of cancer. The Houston-area incubator, a collaboration between Rice University and MD Anderson's Institute for Applied Cancer Science (IACS), is positioned to be perhaps one of CPRIT's greatest successes, bringing together two outstanding Texas academic institutions.

This type of project is exactly what CPRIT was created to encourage and sets an example for the rest of the state. The Houston-area incubator is the first that CPRIT has approved, and certainly won't be our last incubator award.

We accept your offer to resubmit for review the IACS portion of the Houston-area incubator proposal to CPRIT. Please keep in mind that CPRIT's Oversight Committee approved the Incubator RFA in March 2011 with the stipulation that proposals be reviewed by the Commercialization Review Council (CRC). The development of the incubator RFA was a very deliberate and lengthy process by a large group of experts. The incubator RFA is designed for commercial ventures and any proposal submitted must comply with that criterion.

Upon completion of the review and assuming recommendation for funding by the CRC, the proposal will be forwarded for ratification to our Oversight Committee. If approved, we intend to make the grant effective immediately at the funding level and for the period of time recommended by the CRC. While we appreciate your offer to delay funding for twelve months, this is inconsistent with CPRIT policies as applied to our other grant portfolios- prevention and research.

We are confident that the IACS, under the leadership of Dr. Giulio Draetta, working hand-in-hand with the incredible team at Rice University, will rapidly demonstrate commercial viability for which Texas will quickly begin to reap the benefits. I wish to thank you for all you are doing for Texas and the world as President of MD Anderson. Your "moon shot" goal is an inspiration for cancer patients and their families around the globe.

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In Brief

City of Hope Gets \$5.2 Million For Immunotherapy Research

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Francis and Kathleen McNamara Distinguished Chair in Hematology and Hematopoietic Cell Transplantation and director of the T Cell Immunotherapy Research Laboratory. "Central memory T cells have the potential to establish a persistent, lifelong immunity to help prevent brain tumors from recurring."

Researchers at City of Hope previously identified several proteins as potential prime targets for the development of cancer immunotherapies, such as interleukin 13 receptor alpha 2, a receptor found on the surface of glioma cells, and CD19, a protein that is active in lymphoma and leukemia cells.

Both investigational therapies are currently in phase I clinical trials. Forman is the principal investigator for the newly granted study which will develop a T cell that targets different proteins expressed by glioma stem cells. Christine Brown, associate research professor, serves as co-principal investigator, and Michael Barish, chair of the Department of Neurosciences, and Behnam Badie, director of the Brain Tumor Program, serve as co-investigators on the project.

THE INTERNATIONAL IMMUNO-ONCOLOGY NETWORK was announced as a global collaboration between industry and the academic community.

One of the network's objectives is to facilitate the translation of scientific research findings into clinical trials and clinical practice.

In addition to Bristol-Myers Squibb, the network is currently comprised of ten leading cancer-research institutions:

- Clinica Universidad Navarra, Pamplona, Spain
- Dana-Farber Cancer Institute
- The Earle A. Chiles Research Institute (Providence Health & Services)
- Institut Gustave Roussy, Villejuif, France
- Istituto Nazionale per lo Studio e la Cura dei Tumori "Fondazione G. Pascale," Naples, Italy
- Johns Hopkins Kimmel Cancer Center
- Memorial Sloan-Kettering Cancer Center
- The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, London
- The Netherlands Cancer Institute, Amsterdam
- The University of Chicago