M.D. Anderson involved in trial of drug marketed by its president's company

By Eric Berger, Todd Ackerman | July 16, 2012 | Updated: July 20, 2012 9:51am

Aveo Oncology announced in late May that the University of Texas M.D. Anderson Cancer Center would lead clinical tests of its promising new cancer drug.

What the Boston-based company's news release did not say is that M.D. Anderson's president, Dr. Ronald DePinho, is one of its co-founders and owns nearly $8 million worth of its stock. His wife, Dr. Lynda Chin, is one of its scientific advisers.

M.D. Anderson's oversight of clinical trials of the drug AV-203 would violate ethics rules the institution created a decade ago after it failed to tell patients about the financial stake of its then-president, Dr. John Mendelsohn, in his drug Erbitux.

"To me, this is a conflict of interest," Dr. Leonard Zwelling, an M.D. Anderson professor who helped rewrite the ethics rules, said of the Aveo trial. "There is a system that got bypassed here."

DePinho unavailable

An M.D. Anderson spokesman, Stephen Stuyck, denied the institution is the lead site for the trial. Stuyck also denied that DePinho had any knowledge of Aveo's news release.
DePinho was out of the country and unavailable for comment.

However, according to documents obtained by the Houston Chronicle, by late May DePinho had applied for a waiver for the Aveo trial. The waiver, still under review by the UT system, would allow him to bypass the ethics rule that prohibits the president from having any ownership interest in a company whose drug trials are being led by an institution faculty member.

Together, DePinho and Chin own about 600,000 shares of Aveo's stock. DePinho's service on Aveo's board was approved by the UT system prior to his appointment at M.D. Anderson.

Despite M.D. Anderson's assertions, on Monday Aveo twice stood by the news release. M.D. Anderson's Dr. George Blumenschein is "definitely" the study's principal investigator, said Aveo spokesman Rob Kloppenburg.

Later on Monday, after Chronicle inquiries to M.D. Anderson, Kloppenburg changed his statement, saying no lead investigator had been chosen.

**Reviewers surprised**

Internal emails obtained by the Chronicle show that M.D. Anderson was intended to be the lead site. After the press release was issued, Kristofer Griffith, an M.D. Anderson human research manager, asked Blumenschein and a research coordinator, Alisha Thierry, whether M.D. Anderson was in fact the lead site.

"Kris, I did check with the Sponsor (Aveo) and they did indicate that we are the lead site," Thierry replied on May 30.

Emails show that the news release announcing the Aveo trial surprised M.D.
Anderson's ethics committee, which reviews clinical trials for conflicts of interest, as well as lawyers at the institution.

After seeing the release, senior M.D. Anderson legal officer Lori Stiffler wrote to Michelle Colvard, a research manager at the institution, asking, "Does anyone know anything about this 'Clinical Trial for Aveo at MDA'?"

Colvard forwarded Stiffler's query to several M.D. Anderson officials, including Dr. Ralph Freedman, chairman of the hospital's institutional review board.

"I can't see how we can be the lead site," Freedman replied.

M.D. Anderson officials said Monday the matter is on hold until the UT System rules on the waiver request and its institutional review board decides whether to approve it. Stuyck said it is "unlikely" M.D. Anderson will lead the trial, but suggested it is possible the Houston cancer center could be one trial site.

Asked why DePinho would seek a waiver from policies designed to prevent conflicts of interest, Stuyck said, "Dr. DePinho's actions are in keeping with both the letter and spirit of the policy."

An ethicist who has written extensively on conflicts of interest in medicine disagreed.

**Authority on ethics**

Carl Elliott, a professor at the University of Minnesota Center for Bioethics, characterized the conflict of interest in the Aveo trial as alarming. He said M.D. Anderson should better explain why DePinho sought a waiver.

"These responses by M.D. Anderson officials seem deceptive and misleading,"
Elliott said. "The potential subjects in this trial are extremely vulnerable and they deserve an honest explanation."

Founded in 2002 as GenPath Pharmaceuticals, Aveo changed its name in 2005 and went public in 2010 after raising about $150 million from venture capital investors.

Last year, Aveo paid DePinho $241,000 in cash and stock options for his role as director, and he also received $66,667 for his consulting work prior to joining M.D. Anderson.

The value of DePinho's stake in Aveo has increased by about $1 million since he mentioned the company - calling it "one of the more successful biotechs" - in a May television interview on the subject of cancer research.

DePinho soon apologized, saying his reference to the company was inappropriate.

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