

**press release**

## Mark Davis Q&A

### MAKING IT PERSONAL: FINDING A NEW WAY TO TREAT CANCER

*When Mark Davis, a chemical engineer, found out that his wife, Mary, had cancer, helping her survive devastating chemotherapy treatments became his mission. Her treatments became so unbearable that she pleaded with her husband to find a better way. “You can fix this,” she challenged him, and so began a scientific odyssey that led Davis to create IT-101, a revolutionary cancer drug. Their story – and the story of the first trial patient to use IT-101 – is featured in **CURIOUS**, a new series from Thirteen/WNET New York premiering this January on public television (check local listings for premieres in your market). In the following Q&A, Davis discusses the drug he created and the hope it has already brought.*

**Q.** How and why has cancer been so difficult to treat after so many years?

**DAVIS:** Cancer is really not a single disease – it is really over a 100 different types of diseases. What I mean by this is that lung cancer is different from breast cancer that is different of other types of cancer. Additionally, cancer is your own cells “gone mad” so the recognition of them from yourself is very difficult. These and other issues make cancer a very difficult disease to treat. However, the molecular level understanding of cancer is progressing at a very fast pace now and I believe that we will see spectacular advances in the near future as we exploit this new understanding.

**Q.** Please provide a quick background on how you came to develop IT-101.

**DAVIS:** This is the *Curious* story. I am an engineer so my approach was to ask what are the essential features that would need to be done to create a new cancer therapeutic that could overcome some of the current limitations. While one can never completely answer the question, certain issues could be defined. I then began to think about how to design a material and system to address those issues. That approach has yielded IT-101 and other new therapeutics that are now coming along behind IT-101. The key was not to take known materials and try to “bandage them up” to make them work, but rather to start from the beginning and build a system that is designed to function appropriately for the specific job.

**Q.** How does IT-101 differ from traditional cancer treatments? How is it unique?

**DAVIS:** Again, this is the *Curious* story. The way I describe it – it is the first de novo designed cancer medicine to reach humans.

**Q.** Did you have any previous experience with medical or biological research prior to developing IT-101?

**DAVIS:** Yes. My undergraduate training was in chemical engineering and pre-med. One of my undergraduate research projects was on nerve function. However, as a faculty member, I did not work on this until after Mary contracted breast cancer.

**Q.** How is your wife doing now?

**DAVIS:** She is doing fine. At this point, it is the chemo damage that affects her life, e.g., loss of high frequency hearing.

**Q.** Can you briefly outline and explain the FDA's clinical trial process and what the different stages are?

**DAVIS:** Phase I – is it safe and what dose can be given to patients in a safe manner? What are the side effects and are they acceptable? Phase II – first look at how effective it is in a patient population large enough to be able to generate responses that can have statistical significance. Phase III – pivotal studies with large patient populations to see if the proposed therapy (dose level, dose schedule) provides any advance over current therapies.

**Q.** Where does the IT-101 trial stand now?

**DAVIS:** It is finishing the Phase I trial and will be moving into several Phase II trials (Phase I can be for all types of cancer but Phase II has to be in specific cancer types).

**Q.** Were you surprised at the initial success of the trial?

**DAVIS:** Yes. Especially at the first dosing showing effects.

**Q.** Has your research been specific to the kind of cancer your first trial patient, Ray Natha, has?

**DAVIS:** Ray has metastatic pancreatic cancer. IT-101 is not specific to that cancer. Our research has emphasized the creation of new therapeutics that would be broadly applicable to many types of cancer.

**Q.** How have the trial results compared in people with other types of cancer? Have they been similar?

**DAVIS:** Other patients have other cancer types. We are seeing effects in other cancer types but I am not able to provide you specific details.

**Q.** How did your relationship with City of Hope get established?

**DAVIS:** It was through Mary being treated there.

**Q.** How is Ray Natha doing today?

**DAVIS:** Ray is still be treated on compassionate use. He remains stable!

**Q.** What happens to patients after a trial concludes? Do they still have access to the treatments?

**DAVIS:** Thus far, patients who have successfully concluded the six-month trial are placed on

compassionate use.

**Q.** Where can people go for an opportunity to participate in trials of experimental drugs?

**DAVIS:** There is a Web site <http://clinicaltrials.gov/> that lists all the clinical trials ongoing.

**Q.** What are your hopes for the future of cancer treatment? Might there one day be a prophylactic approach to treatment, whereby patients can take preventative or maintenance drugs?

**DAVIS:** As I say, this is my dream – prophylactic use. We are, in fact, working on the concept of maintenance therapy right now. It is the logical step toward ultimately getting to prophylactic use.

**Q.** If all goes well, when do you expect IT-101 to be approved by the FDA and on the market?

**DAVIS:** Three to seven years.

**Q.** Have you ever been featured in a documentary like *Curious*?

**DAVIS:** No.

**Q.** Do you think the kind of visibility PBS will bring to you and your work could help with the FDA approval process, and with funding this and other research?

**DAVIS:** I don't know about the approval process. My guess would be that it can't hurt but I am skeptical that it will really help. I definitely hope that it helps in some way though. At this point, it could help get patients to fill our trials faster and that could ultimately help the approval process move quicker. However, I am sure many positives that I have not thought about will come out of the PBS show.

**Q.** What other research are you working on now?

**DAVIS:** In addition to our work on therapeutics, we are working on creating new materials for moving ions. Why is this important? We are attempting to synthesize materials to make safer and longer-lasting batteries.

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Funding for **CURIOUS** is provided by TIAA-CREF, Peter & Merle Mullin and Stan & Barbara Rawn. **CURIOUS** is a co-production of Thirteen/WNET New York and the California Institute of Technology and is distributed by American Public Television.

**About Thirteen/WNET New York**

Thirteen/WNET New York is one of the key program providers for public television, bringing such acclaimed series as *Nature*, *Great Performances*, *American Masters*, *Charlie Rose*, *Religion &*

*Ethics NewsWeekly, Wide Angle, Secrets of the Dead, NOW With David Brancaccio, and Cyberchase* – as well as the work of Bill Moyers – to audiences nationwide. As the flagship public broadcaster in the New York, New Jersey and Connecticut metro area, Thirteen reaches millions of viewers each week, airing the best of American public television along with its own local productions such as *The Ethnic Heritage Specials, The Thirteen Walking Tours, New York Voices,* and *Reel New York*. Thirteen extends the impact of its television productions through educational and community outreach projects – including the Celebration of Teaching and Learning – as well as Web sites and other digital media platforms. More information can be found at: [www.thirteen.org](http://www.thirteen.org).

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