Promising New Nanomedical Cancer Therapy Also Highlights Tech Transfer, Inventor Says

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If a new approach to cancer therapy, still experimental and in a phase I clinical trial, turns out as well as hoped, the credit will go as much to technology transfer as to scientific acumen.

That's the opinion of Mark Davis, the Schlinger Professor of Chemical Engineering at the California Institute of Technology. Davis's custom-designed nanoparticles for fighting cancer are currently being tested on patients at City of Hope in nearby Duarte, and are now in the planning stages for more extensive phase II trials. The nanoparticles are built to deliver chemotherapy drugs to tumors in such a way that the adverse effects of the drugs on the rest of the body are minimized.

Constructed of a synthetic polymer and a chemotherapeutic drug, the particles are about 40 nanometers in diameter--or less than a thousandth the diameter of a human hair. Just big enough to avoid being washed out of the body by the kidneys, but small enough to pass easily through the new veins and capillaries of a tumor and move throughout it, the nanoparticles enter the tumor cells and unload their chemical cargo at the very spot where the drugs will do the most good. This creates a sort of "FedEx" for cancer treatment delivery.

As a result, the hope is that patients may avoid losing their hair and suffering the nausea commonly associated with traditional chemotherapy.

But Davis says that engineering molecules for the emerging field of nanomedicine has been more than devising a clever means of getting them into the patient through a conventional intravenous drip. Success has also required an effective way of getting the molecules out of the campus lab.

"Research scientists can be very effective in inventing new technologies useful for biomedicine, but we just can't get it to the clinic without help," says Davis. "And most physicians don't know how to do that, either."

The solution for Davis's nanoparticles has been to transition the discovery through a start-up company. "Once you've made the discovery and completed the preliminary animal studies to show that the basic scientific principles work, you still don't really know if it will be effective in humans. So one way to get to the clinic is to take the invention off campus and into a start-up company that hires the people with the proper skills to convert lab materials into "drugs in vials" appropriate for human use and then to test them in clinical trials.

"We designed the particles from first principles and expressly for this application," Davis adds. "Ours is the first one to reach the clinic that is de novo designed as a nanomedicine for cancer, and now that it's being tried on patients, we're actually getting to see how these concepts work in humans."

The company that made the clinical trials possible is Insert Therapeutics, which Davis founded with the help of Larry Gilbert of Caltech's tech transfer office. Insert Therapeutics is based about a half-mile north of campus, and is also responsible for having gotten the green light from the Food and Drug Administration for human clinical trials.

The molecules themselves, though invented on the Caltech campus in

Pasadena, are manufactured by Insert Therapeutics. Once the Phase II trials begin on some hundred patients or so, there likely will be several medical centers involved. So Insert Therapeutics has indeed been a linchpin in the goal of making the therapy available for cancer patients who might benefit.

Neither Davis, Insert Therapeutics, nor City of Hope officials are free to discuss individuals currently undergoing therapy with the new nanoparticles, but Davis says that early results are "very interesting."

"The nanoparticle system was tried on about eight different cancers in animal models, and it has worked well in all of them," he says. "I can't tell you how many humans have undergone the therapy, but it has been used over a spectrum of cancers involving some with very high mortality rates.

"Our approach, even when we were working with animal models, was to do the hard ones first," Davis says. "But I can't overemphasize the importance of having thought, from day one, whether we had the ability to manufacture the polymer once we had designed it."

If all goes well in phase II trials, the therapy will be tried out on the even larger and more extensive phase III trials that are necessary prior to FDA approval.

Davis began the work on the nanoparticles at the request of his wife, who was being treated for breast cancer 10 years ago and suffering from the results of traditional chemotherapy. The work changed the direction of Davis's lab research at Caltech, and his wife remains in remission.

Davis will be featured in "CURIOUS," an upcoming public television documentary filmed at Caltech and the Jet Propulsion Laboratory. Produced by Thirteen/WNET New York, the two-episode documentary

will premiere this October in select markets including New York and Boston, and will air more widely in January.

Source: Caltech