

UCH's Phase I clinical trials program is seeing more long-term survivors with more common cancers

“SUPER SURVIVORS” DEFY ODDS, OFFER HOPEFUL GLIMPSE AT CANCER’S FUTURE *By Todd Neff*

Troy Sinar, diagnosed with advanced-stage lung cancer two years ago at age 34, is more than a survivor.

He’s a “super survivor.”

Sinar, who lives in Centennial with his wife Barbara and three young children, is one of a small but growing number of patients with advanced cancer who have managed to defy the odds, regaining control of their

UCH’s “super survivors” benefit from a broad pool of experimental drugs and guidance from Cancer Center specialists.

disease after they have exhausted all standard treatments.

The emergence of patients like him hinges on the growing use of specifically targeted experimental drugs combined with the exceptional medical expertise of University of Colorado Hospital caregivers, says Ross Camidge, MD, PhD, clinical director of UCH’s Lung Cancer Program.

Camidge has worked with Sinar for more than a year, since Sinar arrived at UCH seeking a second opinion on his lung cancer. He’d already exhausted conventional treatment options for a disease with a historical median survival rate of only four to six months.

A long shot, but a shot. Camidge suggested Sinar enroll in a Phase I clinical trial, the first of three phases of testing mandated by the Food and Drug Administration before a new drug can be licensed. It was a long shot that nonetheless offered Sinar a chance he otherwise would not have had.



Troy Sinar, shown here with his daughter, is one of Ross Camidge’s patients and a “super survivor.”

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In Phase I trials of cancer drugs, little may be known about what dose to give, what the side effects may be and which types of cancer, if any, might respond. Consequently, patients with all different types of cancer may be eligible to join in these studies, provided they are fit enough to act as “test pilots.”

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Phase II trials build on the information learned from the Phase I study, and test the new drug in specific cancers, while Phase III trials compare the new drug to standard therapy. All told, it can take a decade or longer for the FDA to approve a new cancer drug.

About 200 UCH patients participate each year in nearly 30 different Phase I clinical trials, hoping to get access to an effective treatment years before it is more freely available. The breadth of studies makes for an exceptionally deep pool of experimental drugs to choose from, Camidge said. Patients benefit further from the fact that each physician on the hospital’s Phase I team also has a specific area of clinical expertise.

Thus, cancer specialists with detailed knowledge of the basic biology of different cancers can access the pool of Phase I drugs, matching particular trials with particular patients to maximize the chances of success. The approach contrasts sharply with many traditional Phase I cancer programs, where patients may enter these highly experimental clinical trials on a more or less random basis, Camidge pointed out.

Traditionally, patients stay on any given Phase I clinical trials for only six weeks to 12 weeks, or about the length of time it takes for most patients to have a first radiological scan showing the treatment isn’t working.

The traditional success rate for these experimental treatments, especially when allocated randomly, is low, he added. Future patients often get the biggest benefits from Phase I trials.

Renewed hope. Despite these odds, Sinar first started on his Phase I study in early 2008. Over a year later, the dose of drugs has been modified over time to help him cope with long-term treatment, but his disease remains well under control

with little evidence of active cancer showing up on his regularly performed scans, Camidge said.

“I have a belief system that I’m going to survive this,” Sinar said. “I have great hope that, 10 years from now, you and I may be having this same conversation, but talking about super-long-term survivors.”

It’s not an empty hope, Camidge says.

“The essence of treating cancers in the 21st century will be to turn them from death sentences into chronic diseases like diabetes and asthma,” Camidge said. “There will still be reduced life expectancy and complications, but, generally speaking, we want to turn cancer into a footnote in anybody’s life rather than the headline.”

Growing success rate. Gail Eckhardt, MD, head of Medical Oncology at the Cancer Center, who has led UCH’s Phase I clinical oncology program since launching it a decade ago, said there have been occasional long-term survivors since the program’s inception. “Generally,” she reported in an e-mail, “we have more now than we did 10 years ago.”

In the past, she said, Phase I trials often involved new types of standard chemotherapy, and when cancers developed resistance to one, they were often resistant to all. Newer, more targeted drugs tend to breed less resistance and leave the door open for alternate treatments later, she said.

A deeper understanding of the molecular drivers of cancer is also behind the growing number of super survivors, Camidge said. A physician can send a tissue sample off to a laboratory and know, based on genetic sequencing, whether a given patient’s cancer has certain cell receptors that make it a better or worse candidate for a particular drug.

“There is definitely no one answer for everybody. It’s about finding a particular key to the lock of a particular cancer,” Camidge said. “And that lock may keep changing and the drugs to keep it under control in any one individual may need to be changed multiple times over the life of the patient.”

More common cancers. In years past, he added, the rare long-term survivor on a Phase I study tended to have rare cancers, which researchers think may more likely have been caused by a single genetic aberration in cancer cells and are thereby easier to treat, Camidge said.

Common cancers such as lung, breast, gastrointestinal and prostate cancers, in contrast, are believed to be far more complex, with multiple concurrent drivers that evolve over time.

However, a more finely tuned comprehension of the biology of specific cancers is also lengthening the list of survivors such as Sinar with common cancers, said Camidge, who is clearly delighted with the progress.

“I wanted to combine my interests in lung cancer and in Phase I studies precisely to bring new drugs to a disease that was so desperately in need of some good-news breakthroughs,” he said.

Medical science is still far from rendering every cancer a chronic disease. But the successes of super survivors do offer hope. One patient, with pancreatic cancer, has been on the same Phase I clinical trial since October 2006, with the disease almost perfectly controlled, something Camidge called “pretty much unheard of.”

“The last drug for pancreatic cancer was licensed because it prolonged life for six weeks,” Camidge said. “This is a true glimpse of the future for cancer care.”

Visit <http://www.caringbridge.org/visit/troysinar> by May 1 to sign up for “Team Troy” and walk/jog in this year’s “The Gift of Life and Breath” 5K event on May 16. Money raised directly supports the Gary L. and Thelissa Zollinger Early Detection of Lung Cancer Endowment, supporting lung cancer research at the University of Colorado Cancer Center.