



US Oncology Research Translational Oncology Program Enrolls 2,000th Patient in Leading-Edge Phase I Clinical Trials

Program brings novel Phase I oncology trials to community-based cancer centers, providing patients convenient access to advanced treatments

The Woodlands, Texas (February 4, 2016) — [US Oncology Research](#), one of the largest community-based oncology research programs in the United States specializing in oncology clinical trials, announced it has recruited its 2,000th patient to participate in a Phase I clinical trial through its Translational Oncology Program (TOP). Phase I trials present special challenges to both patients and treatment centers and are rarely found in a community setting. The TOP Program, chaired by oncologist and research scientist Daniel Von Hoff, M.D., F.A.C.P., chief scientific officer of US Oncology Research, provides guidance, resources and support so physicians in community-based cancer centers can successfully offer these complex research studies to their patients. Providing access to these advanced clinical trials close to home allows patients to be near family and friends in a familiar setting, supporting optimal outcomes.

“We have reached a great milestone in our Phase I Translational Oncology Program by recruiting our 2,000th patient,” noted Lisa Holland, VP, US Oncology Research. “It is very challenging for practices to manage these complex trials as well as to connect or reach patients when they are looking for access to more options beyond standard therapies, so this is a major accomplishment. I am very proud of the success of the program and proud to support the hundreds of affiliated physicians who lead the program and who work tirelessly for their patients.”

Phase I clinical trials are designed to investigate whether a new drug or treatment, which has proven to be safe for use in animals, may also be safe for people. Participants are often the first to receive a new investigational therapy or a new combination of therapies. Additionally, these advanced trials can only be conducted at qualified locations that have the experience, facilities, and equipment required to conduct such studies. Because of these complexities, Phase I trials are difficult to operate in a community setting and are usually only available at large university hospitals, making the enrollment of 2,000 patients in the TOP program a significant achievement in the cancer community.

“The US Oncology Research TOP Program has pioneered a model for the large scale deployment of Phase I trials across select cities in the nation through community-based cancer centers,” said [Fadi Braiteh, M.D.](#), medical oncologist and director of the TOP Phase I Program for [Comprehensive Cancer Centers of Nevada](#), an affiliate of US Oncology Research. “This allows us to bring the best in new experimental treatment options to our local communities where patients can be treated by expert clinical investigators who utilize these novel therapies, often used for the first time in human subjects, many of which can become, with further development, the newest standard of care in the treatment of specific cancers.”

As a leader in clinical research, Dr. Braiteh serves as principal investigator or co-principal investigator for several clinical research trials, offering these advanced treatments to many of his patients who meet the necessary requirements. One such patient who participated in a TOP Phase I trial was Ms. Patricia Watts, who was diagnosed with advanced bladder cancer four years ago and had few treatment options until seeing Dr. Braiteh.

“My kidney doctor sent me to Comprehensive Cancer Centers of Nevada where I met Dr. Braiteh,” said Ms. Watts. “He said he had a clinical trial for people with my type of cancer that might help me. It sounded promising, so I decided to try it. It took a year for the treatments,” she continued, “but it was well worth the effort. If it had not been for Dr. Braiteh and his clinical trial, I would not be here today. I am cancer free. I want to encourage patients who have decided against participating in a trial to please think again. These treatments could save their lives, just as they saved mine.” Although each patient’s situation is unique,

Ms. Watts became cancer free after receiving a check point inhibitor anti PDL1 which later was awarded by the FDA a breakthrough designation for the treatment of bladder cancers.

Physicians and staff who participate in the TOP program also benefit, often finding the work very rewarding as well as challenging. As director of research at [Willamette Valley Cancer Institute and Research Center](#) and medical director of hematology research for The US Oncology Network, [Jeff Sharman, M.D.](#), was privileged to treat the first CLL patient in the world with ibrutinib in a Phase I TOP trial. Ibrutinib has since transformed treatment for chronic lymphocytic leukemia, the most common form of leukemia found in adults in Western countries. (To see an interview with Dr. Sharman discussing this groundbreaking clinical trial, [click here](#)).

To date, the TOP program has opened more than 130 Phase I trials across the country. It has contributed to the approval of several drugs through Phase I participation including treatments such as azacitidine, ibrutinib, and zydelig.

While finding and enrolling appropriate patients into these complex trials can be quite challenging, several TOP physicians have enrolled a significant number of patients. [Donald Richards, M.D.](#), physician researcher with [Texas Oncology-Tyler](#) and TOP participant since 2005, leads the list of highest enrolling investigators with 266 patients placed into TOP trials as of March 2015. Other high-accruing physicians include:

- Fadi Braiteh, M.D., 258 patients, Comprehensive Cancer Centers of Nevada, TOP participant since 2008
- [Carlos Becerra, M.D.](#), 229 patients, [Texas Oncology-Baylor Charles A. Sammons Cancer Center](#), TOP participant since 2006
- [Jeff Edenfield, M.D.](#), 188 patients, [Greenville Health System](#), TOP participant since 2005
- [Paul Conkling, M.D.](#), 173 patients, [Virginia Oncology Associates](#), TOP participant since 2005
- [Lawrence Garbo, M.D.](#), 130 patients, [New York Oncology Hematology](#), TOP participant since 2006

US Oncology Research has been helping investigators conduct new agent Phase I trials in community-based oncology since 2005 when the Translational Oncology Program was founded. As participants in TOP, physicians and their community-based practices assume a leadership role in the testing of new cancer therapies that provide novel therapeutic treatment and support to patients. The TOP program also provides physicians and nurses experience with the agents early on in the drug development process.

“The Translational Oncology Program physicians and staff are true trailblazers, making an impact against cancer by being on the front line of drug development,” said Dr. Von Hoff. “Enrolling more than 2,000 patients into these TOP Phase I trials is a remarkable achievement that speaks highly of this dedicated team, but the most important thing is that these patients received targeted cancer therapy as early as possible, possibly giving them the best opportunity to attack their disease.”

About US Oncology Research

Supported by [McKesson Specialty Health](#) and [The US Oncology Network](#), US Oncology Research draws from a network of experienced investigators and dedicated clinical staff who specialize in oncology clinical trials. US Oncology Research serves approximately 60 research sites and nearly 165 locations managing about 300 active trials at any given time. Physicians in the research network have enrolled more than 62,000 patients in nearly 1,500 trials since inception in 1992 and have played a role in nearly 60 FDA-approved cancer therapies, nearly one-third of all cancer therapies approved by the FDA to date. For more information visit www.usoncology.com/oncologists.

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