

TGen-TD2-Scottsdale Healthcare breast cancer pilot study shows value of proteomic mapping

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The Side-Out Foundation's breast cancer pilot study, led by the Translational Genomics Research Institute (TGen), Translational Drug Development (TD2) and Scottsdale Healthcare, has shown that cancer patients do better when their treatment is guided by molecular profiling.

Specifically, 52 percent of patients with advanced <u>breast cancer</u> received <u>clinical benefit</u>—meaning their disease was controlled for a longer time—when their cancer was treated based on addressing the abnormal proteins in their tumor, according to the study conducted at the Virginia G. Piper Cancer Center Clinical Trials, a partnership of Scottsdale Healthcare and TGen.

Each patient's treatment was "personalized," meaning that the therapy they received was based on their individual <u>tumor biology</u>.

"This study demonstrates the feasibility of personalized <u>cancer treatment</u>, and shows that this approach merits further investigation in future studies," said Gayle Jameson, Nurse Practitioner at Scottsdale Healthcare's Virginia G. Piper Cancer Center Clinical Trials and the study's Principal Investigator.

"The success of this pilot study will lead to a larger study and hopefully greater clinical benefit for more patients with advanced breast cancer," said Jameson, who presented the results of the study in June at the 2013



American Society of Clinical Oncology (ASCO) in Chicago.

Due to the overwhelmingly positive results, a new study incorporating additional technology for tumor analysis, Side-Out II, will open at the Virginia G. Piper Cancer Center Clinical Trials in the near future for patients with advanced breast cancer.

"The success of our pilot proof-of-concept study has established a firm launching pad for the upcoming Side-Out II study, which involves a more in-depth investigation of tumor biology with an expanded repertoire of tests to direct personalized treatment," said Dr. Jasgit Sachdev, M.D., a breast cancer specialist and Associate Professor at the Virginia G. Piper Cancer Center Clinical Trials.

"By showing the significant advantages of molecular profiling, this pilot study has enabled us to move forward with a project that should strengthen the evidence for using this approach in routine clinical care."

The recent pilot study built on previous studies by Scottsdale Healthcare and TGen that showed the value of guiding treatment based on molecular profiling, in which each patient's tumor was analyzed for protein abnormalities that may "drive" the cancer's growth. The results pointed investigators toward specific genetic changes that might be addressed by specific medications.

Beyond molecular profiling, the pilot study also included mapping proteomic pathways within the tumor tissue so each patient could receive a highly targeted regimen designed to impede their cancer growth.

All of the patients in the recent study had <u>advanced breast cancer</u> that had progressed following multiple previous chemotherapy treatments. Of the 25 patients, 13 received clinical benefit as a result of molecular profiling. For all 25 patients, the therapy selected based on their tumor



analysis was different than what they would have received in their next planned treatment, if they had not participated in the study.

The Virginia G. Piper Cancer Center at Scottsdale Healthcare was the lead site in the 2-½ year pilot study. In addition, patients in the study were treated at Virginia Cancer Specialists, US Oncology, in Fairfax, Vir.; and at Evergreen Hematology & Oncology in Spokane, Wash.

Translational Drug Development (TD2), a TGen company, managed the pilot clinical trial, and will also oversee the follow-on study, Side-Out II.

"This was an exciting study for TD2," said Linda Vocila, BSN, RN, Director of Clinical Operations at TD2 and co-author of the study. "It demonstrates that close collaboration between physicians and scientists leads to greater clinical benefit for patients with <u>cancer</u>."

Two labs analyzed tissue: the Center for Applied Proteomics and Molecular Medicine (CAPMM) at George Mason University in Manassas, Vir.; and Caris Life Sciences in Phoenix.

Provided by The Translational Genomics Research Institute

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