UNC Lineberger discovery goes from the lab to the patient with FDA approval

October 1 2013

A laboratory testing kit that estimates the risk of breast cancer relapse in spite of anti-hormone treatment has received approval from the U.S. Food and Drug Administration (FDA). This technology is based on a gene signature known as "PAM50" originally discovered at UNC Lineberger Comprehensive Cancer Center by Chuck Perou, PhD, professor of genetics and pathology and UNC Lineberger member. Additional UNC inventors included Dr. Joel Parker, research assistant professor of genetics, and Dr. Maggie Cheang, a research associate in the Perou Lab.

"This approval marks more than a decade of work with my fellow researchers and highlights the growing importance of genomic and genetic tests in the oncology clinic," said Perou. "This test is the result of data coming from modern, cutting-edge genomic technologies, and thus it is exciting to see the bench to bedside story fulfilled."

A team of UNC researchers and collaborating researchers from three other institutions—Washington University in St. Louis, the University of Utah and the BC Cancer Agency—designed this test that categorizes breast tumors into one of four main subtypes by looking at the expression of 50 genes. The four types are luminal A, luminal B, HER2-enriched and basal-like. These subtype data are then combined with a standard pathology variable to deliver a "risk of recurrence" score that predicts the likelihood of that patient's disease returning within the next 10 years. In this way, clinicians may now be able to accurately identify those low risk patients for whom standard hormone therapy is

sufficient.

"This is an amazing step in our focus on individualized treatment for our cancer patients," said Shelton Earp, MD, director at UNC Lineberger. "We are shifting from looking at the individual cells of a tumor to a sophisticated analysis into the genetics that drive this disease."

Patients with the luminal A subtype have a low risk of recurrence and do well with long-term anti-hormone therapy that reduces or blocks estrogen, which fuels these tumors. But the other tumor types may require more aggressive measures to prevent relapse, including chemotherapy and sometimes investigational drugs. "This is a very important step down the road towards personalized medicine, and our approach allows us to make this test available to a global market," said Perou.

The test, called ProsignaTM and manufactured by NanoString Technologies, comes with a machine and kit, so patients' tumor samples do not have to be sent to a single laboratory for analysis. Currently the test is being distributed to pathology labs around the world and also is approved for use in the European Union.

The universities jointly hold a pending patent on the technology behind the Prosigna test and have licensed the technology to Bioclassifer LLC. The investigators have joint ownership of Bioclassifer LLC, which licensed the technology to NanoString Technologies.

Provided by University of North Carolina Health Care