

deCODE Launches deCODE BreastCancer™, a Genetic Test to Screen for Risk of the Common Forms of Breast Cancer

Enables women to understand whether they may benefit from more intensive screening, monitoring or preventive drug therapy

REYKJAVIK, Iceland, Oct. 8 /PRNewswire-FirstCall/ -- deCODE genetics today announced the launch of deCODE BreastCancer(TM), a new tool for assessing risk of the common forms of breast cancer. For the first time, a woman concerned about breast cancer can speak with her physician about a genetic test to better understand her lifetime risk of developing the common forms of the disease.

The common forms of breast cancer result from the interplay of genetic as well as environmental and lifestyle factors and represent 95 percent of all breast cancers. These are distinct from the rare and essentially purely inherited forms of the disease due to mutations in the BRCA1 and BRCA2 genes, which cause between 1 and 3 percent of breast cancers. deCODE BreastCancer(TM) is a DNA-based reference laboratory test performed using a simple blood sample or cheek swab, ordered by physicians on behalf of their patients.

"This test is simple and compelling because it provides a woman and her doctor a means of understanding her personal risk of developing the common forms of breast cancer. This information is well-validated, relevant to the vast majority of women, and independent of family history and other known risk factors. Combined with the high public awareness of the importance of screening, advances in magnetic resonance imaging (MRI) technology and the availability of preventive drugs targeting estrogen receptors, I believe this test will help to save lives," said Dr. Kari Stefansson, M.D., Dr. Med., CEO of deCODE.

"DNA-based breast cancer risk assessment has to date been focused on detecting rare mutations that confer very high risk of early onset breast cancer. These are very valuable tests, but they do not measure genetic risk of the common forms of the disease. The DNA markers identified recently by deCODE represent an important step toward filling current gaps in our understanding of breast cancer risk. Ultimately, the goal is to deliver more personalized prevention and treatment for a much greater number of women," said Rebecca Sutphen, M.D., Clinical Geneticist at Moffitt Cancer Center and Advisory Board member at Informed Medical Decisions, Inc., a network of genetic counselors who provide support to physicians and patients using deCODE's tests.

"We speak to many people who are concerned about breast cancer through our 24/7 YourShoes Breast Cancer Support Center," said Margaret C. Kirk, CEO, Breast Cancer Network of Strength (formerly known as YME National Breast Cancer Organization). "We are very interested in all advances that could empower people to take charge of their health care and better understand their risk for developing breast cancer."

Owen Winsett, M.D., founder and director of the Breast Center of Austin, Texas, commented: "I have followed closely the recent scientific discoveries that are incorporated into this test. I am excited to be able to extend my screening and prevention practice, because this test applies to so many more women than the BRCA1 and BRCA2 tests. My patients are eager for this type of risk information and appreciate that the test can be done with a painless inner-cheek swab. I have ordered several tests on an early-access basis and plan to make this test a standard tool for helping me to decide which of my patients may benefit from screening at an earlier age, breast MRIs, and other risk reduction measures. This test helps define individual prevention, which is what so many of my patients want."

The deCODE BreastCancer(TM) test measures seven widely replicated single-letter variations (SNPs) in the human genome that deCODE and others have linked to risk of breast cancer. These SNPs contribute to the incidence of an estimated 60

percent of all breast cancers. The test integrates data from discovery and replication studies published in major peer-reviewed journals and involving nearly 100,000 breast cancer patients and healthy volunteers from many populations, principally of European descent. deCODE and other organizations are conducting replication studies to validate these markers in populations of other continental ancestries.

Women taking the deCODE BreastCancer(TM) test will receive a numerical score representing their relative risk of developing breast cancer in their lifetime compared to that of the general population as well as their personal lifetime risk. According to the American Cancer Society, average lifetime risk for women of European descent is 12 percent. Test scores range from 4.0 times average lifetime risk to less than half, or 0.4-times. The risk assessed by deCODE BreastCancer(TM) is independent of conventional risk factors such as family history of breast cancer in close relatives, age at first menstrual period, pregnancy history, and breast density. Therefore, this genetic risk should be viewed in the context of other risk factors assessed by a woman's physician.

deCODE BreastCancer(TM) can identify the roughly 5 percent of women who are at a greater than 20 percent lifetime risk of the common forms of breast cancer (about twice the average risk in the general population), and the 1 percent of women whose lifetime risk is roughly 36 percent (about three-times average). According to ACS guidelines, women with a lifetime risk of 20 percent or greater should receive annual MRI breast screenings in addition to mammograms, and women at 15 to 20 percent lifetime risk should talk with their doctors about the benefits and limitations of adding MRI screening to their yearly mammogram. With the information provided by the deCODE BreastCancer(TM) test, an additional 15 percent of women may fall within this range of moderately increased risk.

The test also predicts which women are more likely to develop ER-positive breast cancer if they develop cancer at all. This is important because these women may be more likely to respond to prevention strategies with drugs like tamoxifen that target estrogen receptors. The American Society of Clinical Oncology (ASCO) recommends that women with a five-year risk of 1.66 percent or greater should be considered for preventive treatment with tamoxifen.

deCODE BreastCancer(TM) may also be used to modulate the risk profile of the early onset inherited forms of breast cancer in women who have tested positive for risk variants in the BRCA1 or BRCA2 genes.

How to order deCODE BreastCancer(TM)

Additional information and physician order forms for deCODE BreastCancer(TM) can be found at <http://www.decodebreastcancer.com/>. The price of the test is \$1625 dollars and deCODE facilitates filing for reimbursement with commercial insurers. Testing is performed in deCODE's CLIA-registered laboratory, which has analyzed the genomes of hundreds of thousands of people from around the globe.

About Breast Cancer

Breast cancer is the most common cancer and the second leading cause of cancer deaths among women, according to the World Health Organization. The ACS estimates that 182,400 new cases of invasive breast cancer will be diagnosed in the United States in 2008, resulting in more than 40,000 deaths.

Breast cancers are classified as ER-positive or ER-negative according to whether tumors are found to contain estrogen receptors. In women of European descent, approximately three-quarters of breast cancers are ER-positive, and in women of African descent, approximately 50 percent are ER-positive.

Although a substantial portion of risk of breast cancer is inherited, it has taken painstaking research to find genetic variants predisposing to the disease's common forms. The mutations in the BRCA1 and BRCA2 genes conferring very high risk have a less than 0.5 percent frequency in the general population in the United States and Europe, accounting for only 1-3% of all breast cancers.

Identifying and enabling the detection of a substantial proportion of the genetic risk for the common forms of breast cancer is the goal of deCODE's gene discovery work in breast cancer and the deCODE BreastCancer(TM) test. Women who know they are at a higher than average risk of breast cancer can also make proactive lifestyle changes to lower their lifetime risk, according to ACS. These include staying physically active, maintaining a healthy weight, eating healthy foods, and limiting alcohol intake and smoking.

About deCODE

deCODE is a biopharmaceutical company applying its discoveries in human genetics to the development of diagnostics and drugs for common diseases. deCODE is a global leader in gene discovery -- our population approach and resources have enabled us to isolate key genes contributing to major public health challenges from cardiovascular disease to cancer, genes that are providing us with drug targets rooted in the basic biology of disease. Through its CLIA-registered laboratory, deCODE is offering a growing range of DNA-based tests for gauging risk and empowering prevention of common diseases, including deCODE T2(TM) for type 2 diabetes; deCODE AF(TM) for atrial fibrillation and stroke; deCODE MI(TM) for heart attack; deCODE ProCa(TM) for prostate cancer; deCODE Glaucoma(TM) for a major type of glaucoma; and deCODE BreastCancer(TM) for the common forms of breast cancer. deCODE is delivering on the promise of the new genetics. SM Visit us on the web at <http://www.decode.com/>; on our diagnostics site at <http://www.decodediagnostics.com/>; for our pioneering personal genome analysis service, integrating the genetic variants included in these tests and those linked to another twenty common diseases, at <http://www.decodeme.com/>; and on our blog at <http://www.decodeyou.com/>.

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Contacts:

Edward Farmer

+354 570 2819

edward.farmer@decode.is

Gisli Arnason

+354 570 1825

gisli.arnason@decode.is

Marion E. Glick

+1 212 601 8273

marion.glick@porternovelli.com

CONTACT: Edward Farmer, +354 570 2819, edward.farmer@decode.is, or Gisli Arnason, +354 570 1825, gisli.arnason@decode.is, both of deCODE; or Marion E. Glick, +1-212-601-8273, marion.glick@porternovelli.com, for deCODE

Web Site: <http://www.decode.com/> <http://www.decodebreastcancer.com/> <http://www.decodediagnostics.com/>
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