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One Year After Launch, BRCA Share™ Open Data Initiative Reveals New Findings on BRCA Gene Mutations Linked to Hereditary Breast and Ovarian Cancer Risk

Co-Founded by Quest Diagnostics and Inserm, with LabCorp as First Member, BRCA Share is now the Largest Open BRCA Datashare of Curated BRCA Variants Clinically Suitable for Patient Management

MADISON, N.J., PARIS, France, BURLINGTON, N.C. – June 1, 2016 – BRCA Share, a public-private BRCA gene datashare initiative, today announced the public release of a large collection of new data on genetic variants in the BRCA1 and BRCA2 genes. Mutations of these genes raise the risk of breast, ovarian and other cancers. The findings are to be presented today at the 6th International Biennial Meeting of Human Variome Project Consortium (HVP6) held at UNESCO headquarters in Paris.

BRCA Share was co-founded by Quest Diagnostics and the French National Institute of Health and Medical Research (Inserm) in April 2015, with Laboratory Corporation of America® Holdings (LabCorp®) as the first commercial participant. The goal of the initiative is to share clinical, genetic, epidemiological and biological data on BRCA variants, particularly variants of uncertain significance, in order to improve the quality of laboratory diagnostics to better predict which individuals are at risk of developing hereditary breast and ovarian cancers, and to accelerate research on BRCA gene mutations. BRCA Share builds on a BRCA gene-data curation process developed by Inserm, Institut Curie, and Unicancer Genetic Group (UGG) with associated University Hospital Centers, using data developed over a decade of BRCA patient testing by the 16 UGG laboratories in France together with the same associated University Hospital Centers.

This new release adds variants from Quest Diagnostics and LabCorp, two clinical testing laboratory companies operating primarily in the United States, to the collection previously developed by Inserm through the Universal Mutation Database (UMD) project in France. The BRCA Share™ database now contains over 6,200 total BRCA variants, an increase of nearly 30% compared to the previous Inserm UMD database. Of these variants, 334 are newly identified pathogenic or likely pathogenic, increasing by about 20% the total number of pathogenic or likely pathogenic variants to 1,826.

The data include 375 BRCA gene variants whose role in cancer risk was previously uncertain. Of these, 93% are now classified as neutral or likely neutral, while the remaining 7% are now classified as

pathogenic or likely pathogenic. Neutral gene variants are generally considered benign, or non-disease-causing, while pathogenic variants are gene mutations that increase an individual's cancer risk.

The findings are significant because they will contribute to well-informed patient management strategies. A patient with a pathogenic BRCA gene test result may consider options to reduce the risk of developing cancer in the future, including increased screening or prophylactic mastectomy or oophorectomy (removal of breasts or ovaries). Participating commercial laboratories notify physicians of changes in classifications for affected patients.

The BRCA Share Initiative is intended to help scientists, physicians and laboratory experts improve the interpretation of BRCA gene mutations for patient testing and cancer research. With the release of the new set of variants and clinical data, BRCA Share is the largest database providing access to high-quality BRCA genetic data that has been researched and curated to determine clinical significance. Other public BRCA data initiatives collect a mix of curated and uncurated BRCA variant information from participating laboratories. Data curation is an essential step in maximizing the likelihood that data is clinically appropriate and actionable. Variants that are curated have been individually researched and categorized to determine the likelihood that they confer increased cancer risk. Advances in scientific knowledge may lead to new variant discoveries and reclassifications.

"We created BRCA Share to accelerate BRCA science and bring clarity to BRCA patient testing, and in short order, that's exactly what this initiative has done," said Charles (Buck) Strom, M.D., Ph.D., FAAP, FACMG, HCLD, vice president, genetics and genomics, Quest Diagnostics. "This doesn't just benefit patients of Quest, or LabCorp, or Inserm's participating labs. This initiative benefits anyone in the global medical community seeking robust analysis of BRCA genetics based on shared pooling of clinical-grade data and expertise."

"The promise of BRCA Share was to significantly improve BRCA diagnostics and enhance patient care and treatment," said Marcia Eisenberg, Ph.D., chief scientific officer of LabCorp Diagnostics. "BRCA Share has already delivered on that promise, and it will help physicians and patients make more informed monitoring and treatment decisions that can improve health and improve lives."

"BRCA Share demonstrates that public-private data sharing collaborations, funded by commercial parties, can hasten advances in medical research that will benefit patients. This first experience encourages Inserm Transfert to continue its development strategy on health databases whenever it is relevant with industrial partners," said Pascale Augé, Ph.D., CEO, Inserm Transfert.

"In little more than a year, this initiative has provided more than 1,300 new variants and has lifted the veil of uncertainty from 375 variants and identified 334 likely cancer risk variants," added Prof. Christophe Béroud, Pharm.D., Ph.D., leader of the "Genetics and Bioinformatics" research team, Inserm/Aix Marseille University (AMU) UMR_S910.

Research entities and individuals with a research-only focus on BRCA -- including physicians and patients -- can participate in BRCA Share at no charge. The new data is available, beginning today, at http://www.umd.be/BRCA1/ and http://www.umd.be/BRCA2/ . Commercial laboratories may participate in BRCA Share by paying an annual fee to Inserm determined on a sliding scale to fund research and administrative expenses.

Since the launch of BRCA Share, nearly 1,000 scientists from 49 countries have registered to access BRCA Share for research purposes.

To participate, BRCA Share commercial laboratory members must submit their BRCA variant data, which Inserm's variant team then researches and curates. When a variant is curated and/or reclassified, Inserm notifies BRCA Share members and uploads the new data into BRCA Share. BRCA Share's participating laboratories may then begin to use the new data to inform decisions about patient test results.

Members of BRCA Share are free to also share their BRCA data with other datashare initiatives.

About Inserm
The Inserm is the French National Institute of Health and Medical Research. Ranked as the number one academic research institution for biomedical research in the European Union, Inserm operates under the dual auspices of the Ministry of Health and the Ministry of Research. It was created in 1964 as a successor to the French National Institute of Health. Prof. Christophe Béroud leads the "Genetics and Bioinformatics" team in the UMR_S910 research unit, "Medical Genetics & Functional Genomics," directed by Prof. Nicolas Levy. This is a research unit of the French National Institute of Health and Medical Research (Inserm) and the Aix-Marseille University. The laboratory is located at the Medical School of Marseille. www.inserm.fr

About Inserm Transfert
Founded in 2000, Inserm Transfert SA is the private subsidiary of the French National Institute of Health and Medical Research (Inserm), dedicated to technology transfer (from scouting of invention disclosure to industrial partnership). Inserm Transfert also manages European and International research projects, and assists large-scale projects in epidemiology, cohorts, and public health. Inserm Transfert runs a 2M€/year proof of concept fund. The company also supports entrepreneurs in the biotech sector. www.Inserm-transfert.fr

About the Unicancer Genetic Group and associated University Hospital Centers
(Lyon, Montpellier, Nancy, Nantes, Paris)
The UGG is a National Cancer Genetics Network which gathers expert clinicians, biologists, and researchers who contribute to various national and international studies on predispositions to cancers, and develop and implement best practices in genetic diagnosis and care for people at high risk for cancer in partnership with the National Cancer Institute (INCa). BRCA1/2 genetic testing is performed exclusively in France by sixteen laboratories whose diagnosis developments and research studies are performed in the UGG thanks to and through their close proximity with clinical cancer genetics teams belonging also to the UGG.

About Institut Curie
Institut Curie is a private foundation granted charitable status, which combines the largest French oncology research centre and two state-of-the-art hospitals (located in Paris and Saint-Cloud). It is a centre of excellence for the treatment of breast cancer, and paediatric and ocular tumors. The Institut Curie has a longstanding expertise in cancer genetics by combining skills in cancer biology, molecular genetics and genetic epidemiology. It has been founded in 1909 on a model devised by Marie Curie and still at the cutting edge: "from fundamental research to innovative treatments." For more information: www.curie.fr/en.

About Quest Diagnostics
Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 44,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com

About LabCorp
Laboratory Corporation of America® Holdings, an S&P 500 company, is the world's leading healthcare diagnostics company, providing comprehensive clinical laboratory services through LabCorp Diagnostics, and end-to-end drug development support through Covance Drug Development. LabCorp is a pioneer in commercializing new diagnostic technologies and is improving people's health by delivering the combination of world-class diagnostics, drug development and technology-enabled solutions. With net revenue in excess of $8.5 billion in 2015 and more than 50,000 employees in over 60 countries, LabCorp offers innovative solutions to healthcare stakeholders. LabCorp clients include physicians, patients and consumers, biopharmaceutical companies, government agencies, managed care organizations, hospitals, and clinical labs. To learn more about Covance Drug Development, visit www.covance.com. To learn more about LabCorp and LabCorp Diagnostics, visit www.labcorp.com.