Major journal publishes landmark proteomics study demonstrating development of an unprecedented new clinical cardiovascular risk test

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SomaScan® platform study utilizing 32,000 samples showed a 27-protein test is a uniquely superior surrogate for cardiovascular outcomes

BOULDER, Colo., April 12, 2022 (GLOBE NEWSWIRE) -- In one of the largest proteomic studies ever conducted and published April 6 in the journal Science Translational Medicine, scientists at SomaLogic used the SomaScan® Platform to create and validate a 27-protein clinical test model that accurately predicts the 4-year likelihood of myocardial infarction, heart failure, stroke or death. The model was found to outperform current clinical approaches, and was reliably sensitive to longitudinal changes in risks from multiple mechanisms, including lifestyle changes and various classes of drugs – meeting a key requirement for a useful surrogate endpoint. No single known cardiovascular biomarker can currently predict heart disease in this manner, and this test is available for clinical use now under a laboratory developed test designation (LDT).

SomaLogic scientists used the SomaScan® Assay to measure levels of approximately 5,000 proteins in more than 32,130 archived blood samples, deriving more than 160 million protein measurements to develop and validate the new test. The samples represented 22,849 participants across 9 clinical studies.

Using machine learning, the researchers developed a 27-protein model, which outperformed traditional and enhanced clinical models based on age, sex, race, total cholesterol, HDL cholesterol, blood pressure, diabetes and smoking. The test performed consistently well across ethnicities, races, age ranges, geographic regions and comorbidities and was sensitive to elevated cardiovascular risks from diseases and conditions where epidemiologic evidence showed elevated event rates traditional diagnostic approaches failed to detect. Adding clinical risk factors to the protein model had little or no added value.

“We are excited about the results of this study because a proteomic surrogate endpoint for cardiovascular events could be used for assessing clinical safety for many new drug mechanisms in different therapeutic areas, as well as accelerating the development of new cardiovascular drugs,” said SomaLogic Chief Medical Officer Stephen A. Williams. “In addition, it could play a valuable role in health care to allocate resources to patients most at risk for a cardiovascular event.”

Surrogate endpoints are often used in clinical trials when outcomes, like a stroke, take a long time to study. Some of these surrogate endpoints are accepted by the FDA as a substitute for a clinical outcome during drug approval (the 27-protein model described in this recent paper has not yet been evaluated by FDA). Examples of FDA-accepted surrogates in cardiovascular disease include blood pressure and cholesterol, but these measures are not relevant to many of the new cardiovascular drugs.

Dr. Peter Ganz, a Professor of Medicine at the University of California, San Francisco and co-authored the paper with Williams, views the 27-protein test as, “potentially transformative in drug development and in patient care.” He said, “The development of a new drug for cardiovascular care can cost as much as several billion dollars, with a high failure rate. A surrogate for cardiovascular outcomes, such as the 27-protein model, has the potential to weed out ineffective or harmful drugs early in their development, reducing the costs of drug development and risks to human subjects enrolled in clinical trials. In addition, in clinical settings, the 27-protein model may accurately identify individuals at the highest risk to whom expensive therapies or therapies with potential side effects can be rationally allocated.”

The international research team on the paper included scientists and clinicians from SomaLogic, Johns Hopkins University, Baylor College of Medicine, the University of Basel Cardiovascular Research Institute, University of Zurich, Norwegian University of Science and Technology, University of Oxford, Duke University, University of Glasgow, University of Newcastle upon Tyne, Tohoku University, Icahn School of Medicine at Mount Sinai, University of Oslo, Boulder Community Hospital and Zuckerberg San Francisco General Hospital/University of California, San Francisco.

The risk prediction test described in the manuscript is a central feature of SomaLogic’s Proteomics for Personalized Medicine Initiative, where multiple U.S. health systems are determining how it can impact the allocation of newer, more expensive, cardioprotective drugs and impact clinical practice in other ways. It is also already being used for preventative health management in some self-pay and cardiology health practices.

SomaLogic can currently run 7,000 protein measurements on a single 55 microliter plasma or serum sample, has plans to enable measurement of 10,000 proteins in the next year and has run more than 450,000 samples to date. Several additional clinical tests for renal, diabetic and liver diseases have been developed by SomaLogic using this approach, and are also currently available as LDT designated tests and many others are under development.

About SomaLogic
SomaLogic (Nasdaq: SLGC) seeks to deliver precise, meaningful, and actionable health-management information that empowers individuals worldwide to continuously optimize their personal health and wellness throughout their lives. This essential information, to be provided through a global network of partners and users, is derived from SomaLogic’s personalized measurement of important changes in an individual’s proteins over time. For more information, visit www.somalogic.com and follow @somalogic on Twitter.

SomaSignal™ tests are developed and their performance characteristics determined by SomaLogic Operating Co., Inc. They have neither been cleared nor approved by the US Food and Drug Administration. SomaLogic operates a Clinical Laboratory Improvement Amendments (CLIA) certified, and College of American Pathologists (CAP) accredited laboratory.

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