Landmark Study Shows GeneSight® Test Led to Significant Improvement in Mental Health Outcomes for Patients with Major Depressive Disorder

Data Presented at APA Show 50 Percent Improvement in Remission and 30 Percent Improvement in Response for GeneSight versus Treatment as Usual (TAU)

SALT LAKE CITY, May 07, 2018 (GLOBE NEWSWIRE) -- Assurex Health, a wholly-owned subsidiary of Myriad Genetics, Inc. (NASDAQ:MYGN), today announced that results from a large, well-controlled pharmacogenomics study in patients with major depressive disorder (MDD) were presented at the American Psychiatric Association annual meeting in New York City. The key finding is that patients were 50 percent more likely to achieve remission and 30 percent more likely to respond to treatment when their medication selection was guided by the GeneSight® Psychotropic genetic test.

"We now have the results from the largest-ever pharmacogenomics clinical study in patients with moderate-to-very severe depression," said Bryan Dechairo, Ph.D., executive vice president of clinical development, Myriad Genetics. "The important news here is that when doctors used the GeneSight genetic test to guide their selection of antidepressants, patients experienced significantly higher rates of response and remission as well as better overall symptom relief."

The key data are summarized below. Follow Myriad on Twitter via @MyriadGenetics and @GeneSight and stay informed about conference news and updates by using the hashtag #APAAM18.

**Title:** Combinatorial pharmacogenomics significantly improves response and remission for major depressive disorder: A double-blind, randomized control trial.

**Presenter:** John Greden, M.D., University of Michigan Comprehensive Depression Center.

**Date:** Monday, May 7, 2018, 10:00 a.m. ET.

**Poster Location:** P5-110.

This 24-week landmark study included 1,167 patients with moderate-to-very severe depression who had failed at least one antidepressant medication. Patients were divided into two treatment arms: the GeneSight Psychotropic test arm (n=560) in which clinicians used GeneSight test results to guide treatment decisions and a treatment-as-usual arm (n=607) in which psychiatrists and primary care physicians prescribed medication as they normally would without the benefit of genetic testing. The Hamilton Depression scale (HAM-D17) was used to measure the key endpoints of remission (achieving a HAM-D17 score <7), response (50 percent decrease in HAM-D17 from baseline) and symptom improvement (percent change in HAM-D17 from baseline) at week 8. The durability of patients' mental health outcomes was assessed at week 24.

"This is the first-ever prospective, large-scale, double-blind, randomized controlled trial evaluating combinatorial pharmacogenomics testing in patients with treatment-resistant major depressive disorder," said John Greden, M.D., principal investigator, executive director of the University of Michigan's Comprehensive Depression Center and an unpaid consultant to Assurex Health. "GeneSight-guided care was compared to physicians' optimized treatment plans. The results indicate that patients fared significantly better with the pharmacogenomics approach than with usual care, despite this being a difficult-to-treat patient population. The improvements continued to increase as the study was extended to 24 weeks."

The study results demonstrate that at week 8, individuals in the GeneSight cohort were 50 percent more likely to achieve remission and 30 percent more likely to achieve treatment response compared to those in the TAU group. The GeneSight-treated cohort also demonstrated higher symptom improvement which approached statistical significance (Chart 1).

Importantly, remission and response rates continued to improve in the GeneSight treatment arm through week 24 (Chart 2) as did symptom improvement (Chart 3), demonstrating the long-term durability of the results.

A PDF of all three charts accompanying this announcement is available here: [http://resource.globenewswire.com/Resource/Download/902eccc6-a732-411d-84c3-2bb1aa10c7e8](http://resource.globenewswire.com/Resource/Download/902eccc6-a732-411d-84c3-2bb1aa10c7e8)

"Achieving response and remission are the ultimate goals of treating patients with depression," said Dr. Greden. "These results demonstrate promise for a pharmacogenomics approach to help improve short- and long-term response and remission rates in depressed adults compared to clinicians' usual approaches to medication selection."
About Major Depressive Disorder

Major depressive disorder (MDD) is one of the most common mental disorders and can result in severe impairments that interfere with or limit one’s ability to carry out major life activities. MDD is defined as a period of two weeks or longer during which there is either depressed mood or loss of interest or pleasure, and at least four other symptoms that reflect a change in functioning, such as problems with sleep, eating, energy, concentration, self-image or recurrent thoughts of death or suicide. The National Institute of Mental Health estimates that more than 16 million adults in the United States had at least one major depressive episode in the past year and the World Health Organization (WHO) categorizes clinical depression as the world’s leading cause of disability.

About GeneSight

GeneSight is a laboratory-developed pharmacogenomic test that uses cutting-edge technology to measure and analyze clinically important genomic variants in the treatment of psychiatric disorders. The results of the GeneSight report can help a clinician understand the way a patient’s unique genomic makeup may affect certain psychiatric drugs. The analysis is based on pharmacogenomics, the study of genomic factors that influence an individual’s response to drug treatments, manufacturers’ FDA approved drug labels, peer reviewed scientific and clinical publications, and proven drug pharmacology. Quick turnaround time, combined with a customized report of the patient’s genomic makeup, clinical experience, and other factors can provide information to help a physician make personalized drug treatment choices for each patient. For more information about GeneSight, please visit www.genesight.com.

About Myriad Genetics

Myriad Genetics Inc., is a leading personalized medicine company dedicated to being a trusted advisor transforming patient lives worldwide with pioneering molecular diagnostics. Myriad discovers and commercializes molecular diagnostic tests that: determine the risk of developing disease, accurately diagnose disease, assess the risk of disease progression, and guide treatment decisions across six major medical specialties where molecular diagnostics can significantly improve patient care and lower healthcare costs. Myriad is focused on five strategic imperatives: build upon a solid hereditary cancer foundation, growing new product volume, expanding reimbursement coverage for new products, increasing RNA kit revenue internationally and improving profitability with Elevate 2020. For more information on how Myriad is making a difference, please visit the Company's website: www.myriad.com.

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Safe Harbor Statement

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the study showing the GeneSight test leads to significant improvement in mental health outcomes for patients with major depressive disorder; the percent likelihood of response to treatment and percent likelihood to achieve remission when patient medication selection is guided by the GeneSight test; the study results demonstrating the benefits of the GeneSight test in improving short- and long-term response and remission rates in depressed adults compared to clinicians’ usual approaches to medication selection; and the Company's strategic directives under the caption “About Myriad Genetics.” These “forward-looking statements” are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described or implied in the forward-looking statements. These risks include, but are not limited to: the risk that sales and profit margins of our existing molecular diagnostic tests and pharmaceutical and clinical services may decline or will not continue to increase at historical rates; risks related to our ability to transition from our existing product portfolio to our new tests; risks related to changes in the governmental or private insurers’ reimbursement levels for our tests or our ability to obtain reimbursement for our new tests at comparable levels to our existing tests; risks related to increased competition and the development of new competing tests and services; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and pharmaceutical and clinical services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and pharmaceutical and clinical services, including our ability to successfully generate revenue outside the United States; the risk that licenses to the technology underlying our molecular diagnostic tests and pharmaceutical and clinical services tests and any future tests are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with operating our laboratory testing facilities; risks related to public concern over our genetic testing in general or our tests in particular; risks related to regulatory requirements or enforcement in the United States and foreign countries and changes in the structure of the healthcare system or healthcare payment systems; risks related to our ability to obtain new corporate collaborations or licenses and acquire new technologies or businesses on satisfactory terms, if at all; risks related to our ability to successfully integrate and derive benefits from any technologies or businesses that we license or acquire, including but not limited to our acquisition of Assurex, Sividon and the Clinic; risks related to our projections about the potential market opportunity for our products; the risk that we or our licensors may be unable to protect or that third parties will infringe the proprietary technologies underlying our tests; the risk of patent-infringement claims or challenges to the validity of our patents; risks related to changes in intellectual property laws covering our molecular diagnostic tests and
pharmaceutical and clinical services and patents or enforcement in the United States and foreign countries, such as the Supreme Court decision in the lawsuit brought against us by the Association for Molecular Pathology et al; risks of new, changing and competitive technologies and regulations in the United States and internationally; the risk that we may be unable to comply with financial operating covenants under our credit or lending agreements; the risk that we will be unable to pay, when due, amounts due under our credit or lending agreements; and other factors discussed under the heading "Risk Factors" contained in Item 1A of our Annual report on Form 10-K for the fiscal year ended June 30, 2017, which has been filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

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