UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 4, 2019

MYRIAD GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 0-26642 (Commission File Number) 87-0494517 (IRS Employer Identification No.)

320 Wakara Way Salt Lake City, Utah 84108 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (801) 584-3600

Not Applicable (Former name or former address, if changed since last report)

	he appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General ion A.2. below):
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
	e by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of urities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emergi	ng growth company \square
	nerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial ring standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 7.01 Regulation FD Disclosure

On January 4, 2019, Myriad Genetics, Inc. ("Myriad" or the "Company") held a conference call to discuss the GUIDED study publication in the *Journal of Psychiatric Research* along with the other supporting clinical evidence for the GeneSight test. A copy of the slide presentation and press release announcing the GUIDED study publication are furnished as Exhibit 99.1 and 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Safe Harbor Statement

This communication, including the exhibits attached hereto, contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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.

ITEM 9.01 Financial Statements and Exhibits.

(d)

Exhibit
NumberDescription99.1Slide presentation dated January 4, 2019.99.2Press release dated January 4, 2019.

The exhibit(s) may contain hypertext links to information on our website or other parties' websites. The information on our website and other parties' websites is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

In accordance with General Instruction B-2 of Form 8-K, the information set forth in Item 7.01 and in Exhibits 99.1 and 99.2 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MYRIAD GENETICS, INC.

Date: January 4, 2019

By: /s/ R. Bryan Riggsbee

R. Bryan Riggsbee

Executive Vice President, Chief Financial Officer



Review of GeneSight® Supporting Clinical Data

January 4, 2019



Forward Looking Statements

Some of the information presented here today may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company. These statements are based on management's current expectations and the actual events or results may differ materially and adversely from these expectations. We refer you to the documents the Company files from time to time with the Securities and Exchange Commission, specifically, the Company's annual reports on Form 10-K, its quarterly reports on Form 10-Q, and its current reports on Form 8-K. These documents identify important risk factors that could cause the actual results to differ materially from those contained in the Company's projections or forward-looking statements.



Overview of Clinical Studies in Depression



Overview of Clinical Studies in Depression

- Studies typically use subjective patient assessment by questionnaire (HAM D-17 score) as the clinical measure of depressive symptoms
- Three different endpoints are calculated from changes in these scores: Remission, Response, and Symptom Improvement
- · APA guidelines state that Remission is the only acceptable goal of treatment
- · Payers assessed on Remission and Response as part of HEDIS scores

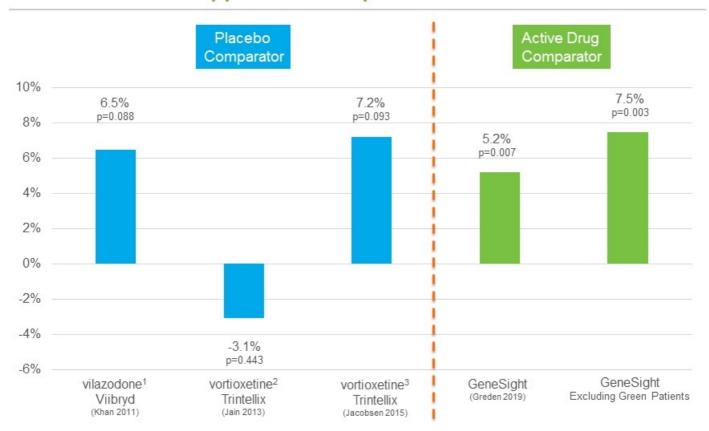
40 consecutive antidepressant studies submitted to FDA in past 20 years

- No FDA approval was based upon an active drug comparator arm and most enrolled treatment-naïve patients (not more difficult treatment-resistant patients)
- Only 13% of trials showed statistically significant improvement in remission over placebo
- Only 30% of trials showed statistically significant improvement in response over placebo
- Only 70% of trials showed statistically significant improvement in symptoms over placebo

Patient Name	Today's Door
The HAM D is designed to rate the severity of depression in score on the first 17 payment.	partients. Although it contains 21 areas, calculate the patient's
DEPERSED MOOD (Gloony annuels, posinities about the future, feeling of sedime, sundancy to weep) 0 = About, 1 = Sudment est. 2 = Occasional weeping 3 = Frequent weeping 4 = Estimate graphous	INSOMNIA - Delayed (Walang in each boars of the morning and soulde to fall along agains) 0 = Along 1 = Occasional 2 = Frequent
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4. INSOMNIA - Irenal (Diffushy to felling aloop) 0 - Alarest 1 - Occasional 2 - Frequent	4 = Complete staper 8. AGITATION (Glodinounus suscissed with analony) 0 = Alasses 1 = Consistend
INSOMNIA - Modile (Complains of being review and datashed during the sight. Waking during the night.) 0 = Absent 1 = Occasional 2 = Frequent	T = Erequent 10. ANXIETY - PSYCHIC 0 = No difficulty 1 = Session and outsidility 2 = Warying about autour nation 3 = Agareteenine annuale 4 = Foot



Comparing Improvement in Remission Rates for GeneSight vs. Most Recent FDA Approved Therapeutics



^{1 -} data using the HAM-D17 depression rating scale



^{2 -} data using the Montgomery-Asberg depression rating scale

^{3 -} data using the Montgomery-Asberg depression rating scale, 10mg dose

GeneSight Clinical Utility Studies Prior to GUIDED

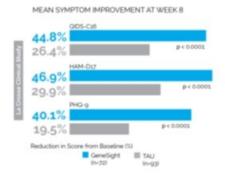


Multiple Prior Studies Showing Clinical Utility of GeneSight

La Crosse Study

Key Findings:

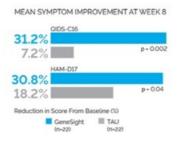
- 70% improvement in depressive symptoms (p<0.0001)
- GeneSight group 2.1x more likely to respond to medication
- Significantly higher patient satisfaction in the GeneSight arm



Hamm Study

Key Findings:

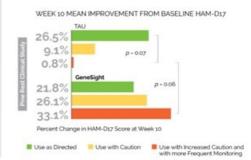
 There was a four-fold greater improvement in symptoms at week 8 in the GeneSight guided group compared to the TAU arm



Pine Rest Study

Key Findings:

- GeneSight guided arm had response and remission rates more than 2x TAU group
- GeneSight predicted which patients would have poor outcomes based on gene/drug interactions





GUIDED Study

Publication Overview

Largest Double-Blind RCT of Pharmacogenomics in Mental Health



Compared ~1,200 patients with MDD who have failed one previous medication receiving GeneSight®-guided therapy to those receiving treatment-as-usual (TAU)





60 study sites including nation's leading academic institutions



UTSouthwestern Medical Center



Assessed Hamilton Depression Rating Scale 17 (HAM-D17) scores from baseline to eight weeks using blinded central rater





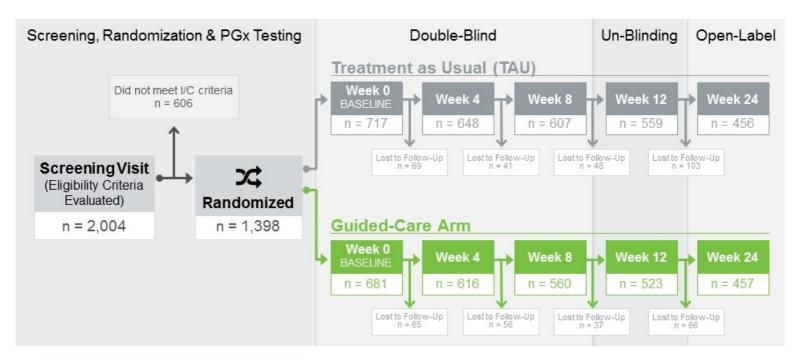
Evaluated **remission** (HAM-D17 score ≤7), **response** (HAM-D17 reduction ≥50%), and **symptom improvement** (reduction in HAM-D17)







GeneSight GUIDED Study Schema



Study schema and participant enrollment in the peer-protocol cohort



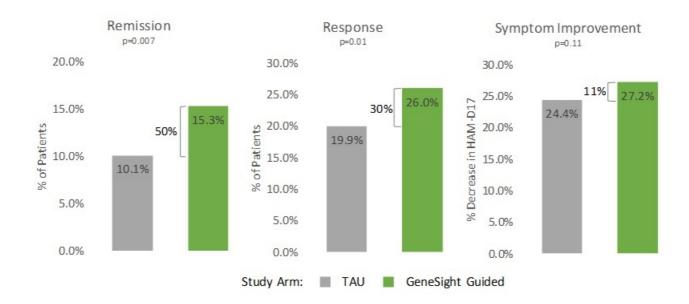
GeneSight Test Report is Easy to Use and Understand



Patient, Sample DOS 102/1804 Cride Noviber: 8/099 Report Date: 8/090/05 Reference: 1486/JP	GEN		INTER	ACTIO	NS		ire? Call 855.	
	-		AS DIRECTE	0				
	CYPIA2	CYPUBE	C1P2C18	CYPOCS	CYPSA4	CYPODE	UGTIM	UGTSB1
ANTICEPRESSANTS								
desvenialistine (Prietig [®])					•			
levominacipren (Fetzime*)			0		•	•		
viazodone (Vibryd*)			0		•	•		
ANKIOLYTICS								
elprepolem (Keneu ^a)					•			
buspirone (Buspert)					•	•		
chlordistrepoxide (Librium*)	0				•			0
dishazapam (Klonopinf)					•			
disrepete (Trenseref)	0				•			0
eszopicione (Junester)				•	•			
lorszepam (Atkranff)								0
cuszepam (Sersu ^a)								0
temacepam (Restori*)		0		•	•			0
zolpidem (Ambienf)	0		0	•	•	•		
ANTIPSYCHOTICS								
ssenapine (Saphyle [®])	0		0		•	•	•	
lurasidone (Latudar)					•			
palperitions (Invage*)					•	•		
Districana (Navana [®])	0							
pigraeidone (Geodon [®])	0				•			
MOOD STABILIZERS								
(artemangine (Tegretoff)		0			•			
oxcertezapine (invege*)		-			-			
valproic aciditivalproes (Depakola ⁸)		0		•			•	
	800	MATE CE	e-censore	TERACTO				
	CYPIAZ	СУРОВИ	CYPOCIA	Суроса	CYPSA4	СтРООВ	UGTSA4	UST381
ANTICEPRESSANTS					50.00			
bupropion (Aleibutenn)		0			•	•		
citalogram (Calaus*)			0		•	•		
eactiniopram (Leuspro*)			0		•	•		
fuetin (Pan 1)			0	•	•	•		
sertraine (Zoioth)		0	0	•	•	•		
venialscine (Effectr ^a)	_	-	0	•	•	•		
Variation was found to patient generation that or								



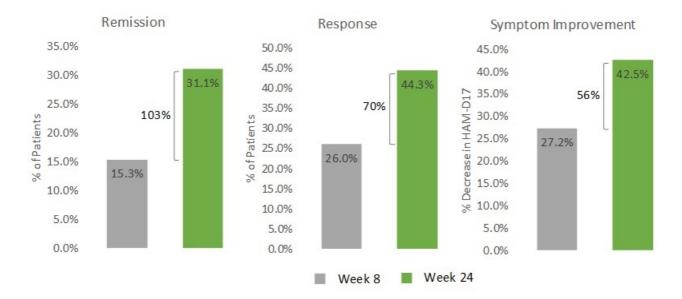
GUIDED Results Compared to Optimized Active Drug Arm





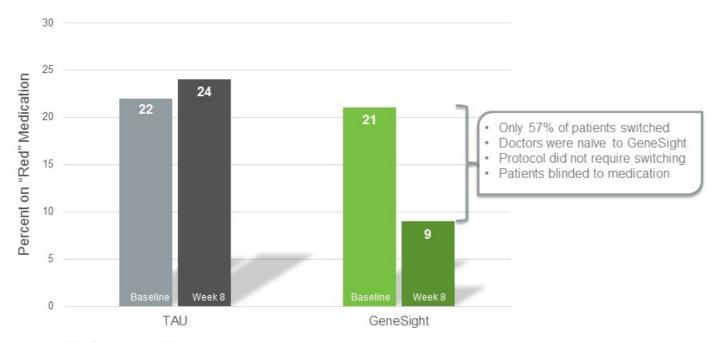
GeneSight-Driven Outcomes are Durable and Improve over 6 Months

- Over 6 months durability
- Remission doubled during open-label period





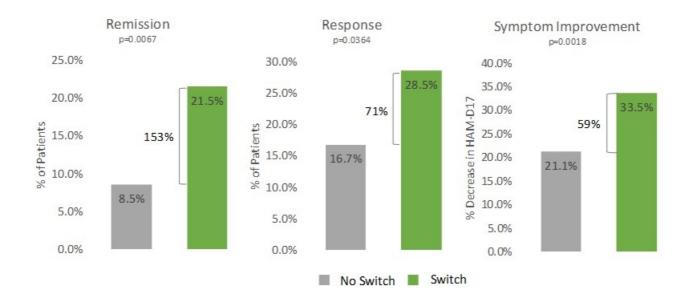
Change in "Red" Medication Use by Study Arm



TAU physicians did not improve ending with more patients on red medications



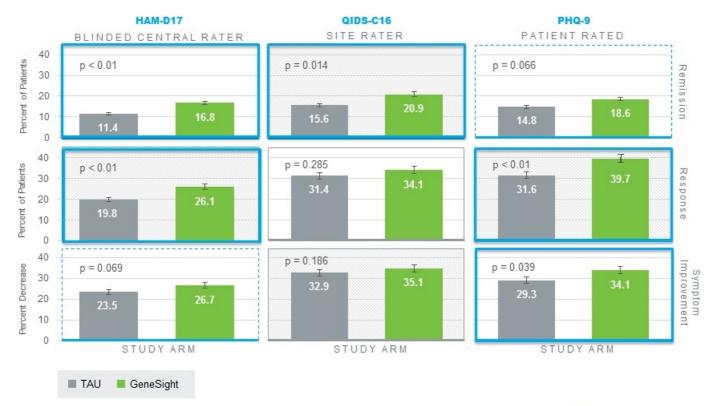
Outcomes for Patients Switching From "Red" Medications





Endpoints for ITT* Population in 3 Depression Instruments

Three Endpoints Better in All Instruments and Statistically Significant In 1+ Instruments

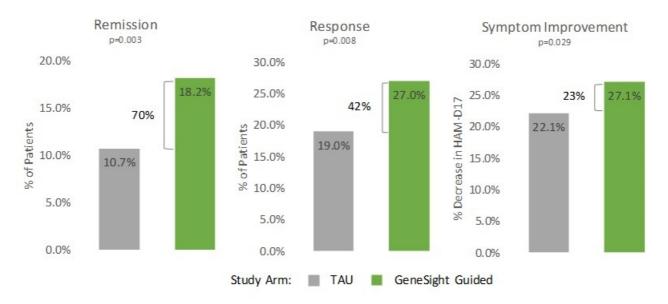


genesight' 15 |

ITT = Intent To Treat | HAM-D17 = Hamilton Rating Scale for Depression
QIDS-C16 = Quick Inventory of Depressive Symptomology | PHQ-9 = Patient Health Questionnaire

Endpoints Highly Statistically Significant When Excluding "Green" Patients

Excludes 30% patients entering on genetically appropriate medications with no expected GeneSight benefit



ITT Population: GeneSight (n=357); TAU (n=429)



IMPACT Study

Publication Overview



IMPACT Study Design

- Goal was to compare outcomes of patients with major depressive disorder treated by either psychiatrists or primary care physicians using GeneSight to guide therapy selection
- Performed in cooperation with the Canadian Centre for Mental Health and Addiction (CAMH)
- · Open label study
- · All patients received GeneSight
- Primary endpoint was the Beck's Depression Inventory performed at 8 weeks
- Enrolled 1,871 total patients 810 treated by primary care providers and 1,061 treated by psychiatrists
- Patients in the primary care and psychiatrist cohorts were deemed to have no clinically meaningful differences
- Data important for Medicare to expand LCD to primary care physicians





Clinical Outcome	Primary Care Physicians	Psychiatrists	% Difference	p-Value
Remission Rates	19.5%	12.0%	63%	<0.01
Response Rates	30.1%	22.3%	35%	<0.01
Symptom Improvement	31.7%	24.9%	27%	<0.01



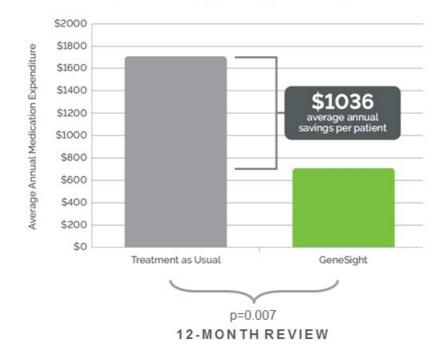
Health Economic Data

Publication Overview



Medco Prescription Drug Study

Evaluated prescription drug claims data from 13,048 patients



Total medication costs were
reduced per patient
when treatment was guided by
GeneSight

GeneSight-guided patients experienced significant increases in adherence and significant reductions in polypharmacy

Winner JG, et al. Curr Med Res Opin 2015; 18:1-30. (Medco) (n=2168; n=10,880 for TAU group; 5-to-1 match)



Union Health Service Healthcare Utilization Study

\$1,556 in healthcare service savings for each patient on GeneSight



ANALYZED COMMERCIAL CLAIMS

Red-bin patients had

- >4-fold more disability claims (p = 0.013)
- >20 workplace absence days (p = 0.024), compared to green- (p = 0.04) or yellow-bin (p = 0.1) patients

Compared to green- or yellow-bin patients, red-bin patients had

- 67% more general medical visits* (p = 0.039)
- 69% more total healthcare visits** (p = 0.014)

Healthcare-related cost***

- Green bin \$3,453 (p = 0.024)
- Yellow bin \$3,426 (p = 0.027)
- Red bin \$8,627, yielding an average annual increase in healthcare cost of \$5,188

Winner JG, et al. Transl Psychiatry 2013; 3:e242. (Union Health Service) (n=96) *General medical visits is defined as all non-psychiatric office visits.

**Total healthcare visits includes all medical visits, plus psychiatric and ER visits.



^{***}Mean healthcare-related cost calculated during previous 12-month period.

Positive ROI with GeneSight



- Winner JG, et al. Curr Med Res Opin 2015; 31(9):1633-43. (Medco) (n=2168; n=10,880 for TAU group; 5-to-1 match) Winner JG, et al. Transl Psychiatry 2013; 3:e242. (Union Health Service) (n=96)



Optum Health Study Design

Patient Demographics:

- 18+ years old with psychiatric disorder (n=683, 205 with GeneSight, 478 with TAU)
- Began psychotropic medication with none taken previous 180 days
- Failed first medication and began second following GeneSight results



Utilized claims from Single Payer Database compiled by OptumInsight, Inc. comprising approximately 25 million members nationwide





Provided costs and budget impact associated with GeneSight Psychotropic testing for major commercial health plan



Defined costs as total payments made to providers for treating psychiatric disorders (depression, anxiety, bipolar disorder, panic disorder, PTSD, premenstrual dysphoric disorder, OCD, schizophrenia)



Compared members with GeneSight-guided care (CPGx cohort) to those who received treatment-as-usual (TAU cohort)



Calculated payer amounts for each cohort over 12 month episode of care

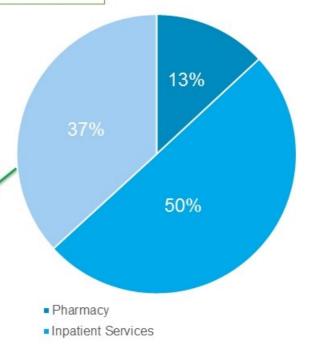


Optum Health Study Results

>\$6,000 in total 12-month savings for patients with MDD

	GeneSight	TAU	Savings
All Patients	\$17,627	\$23,132	\$5,505 (p=0.0004)
Patients With MDD	\$18,741	\$24,971	\$6,050 (p=0.009)

Savings do not include productivity improvements



Outpatient Services & Professional Services



HEDIS Scores Another Motivation For Payers With GeneSight

- Healthcare Effectiveness Data and Information Set (HEDIS) is a comprehensive set of standardized performance measures designed to provide purchasers and consumers with the information they need for reliable comparison of health plan performance
- Behavioral health is an important component of HEDIS scores and for depression the key metrics utilized are remission and response measures
- · These metrics could be used in the future to determine Star Ratings for health insurance plans
- Medicare Advantage plans can receive additional reimbursement if they have high Star Ratings. Plans with consistent low ratings are discontinued from Medicare Advantage

Depression Remission or Response for Adolescents and Adults (DRR) - First implemented in HEDIS 2017.

The percentage of members 12 years of age and older with a diagnosis of depression and an elevated PHQ-9 score, who had evidence of response or remission within 4–8 months after the initial elevated PHQ-9 score.

Denominator: All members ≥12 years of age with a diagnosis of major depressive disorder or dysthymia who had an initial elevated PHQ-9 score of >9.

Numerator: A follow-up PHQ-9 score documented at 4–8 months after the initial elevated score; a PHQ-9 score <5 documented at 4–8 months following the initial elevated score (Remission); a ≥50% reduction in the PHQ-9 score documented at 4–8 months following the initial elevated score (Response).



Conclusion & Next Steps



Key Takeaways From Clinical Studies

- ✓ The GUIDED study is the fifth favorable clinical study and the first blinded, prospective study
- ✓ GeneSight led to a 50% increase in remission rates, 30% increase in response rates, and 11% improvement in symptoms with remission and response achieving statistical significance
- Excluding patients entering on "green medications", GeneSight led to a 70% increase in remission, a 42% increase in response, and a 23% improvement in symptoms, all of which were statistically significant
- ✓ The results continued to improve over the 24 week study period with remission rates increasing to 31%, response rates increasing to 44%, and symptom improvement reaching 43%
- ✓ Patients switching from red medications compared to those that did not saw 153% higher remission rates, 71% higher response rates, and 59% improvement in symptoms and all were highly statistically significant
- ▼ The IMPACT study showed primary care physicians had results even better than psychiatrists when using GeneSight
- ✓ Multiple health economic studies demonstrated significant health care savings



Next Steps

- Begin the tech assessment process with major national payers and request out-of-cycle reviews where appropriate
- ✓ File formal reconsideration request with Medicare to expand LCD to primary care
 physicians
- ✓ Continue to publish numerous additional GUIDED studies with key opinion leaders
- ✓ Pursue professional guidelines and position papers supporting GeneSight
- ✓ Develop primary care launch plan and direct to consumer initiative to be implemented after expanded reimbursement





News Release

Media Contact: Ron Rogers Investor Contact: Scott Gleason (801) 584-3065(801) 584-1143

rrogers@myriad.com sgleason@myriad.com

GeneSight® GUIDED Study Published in the Journal of Psychiatric Research

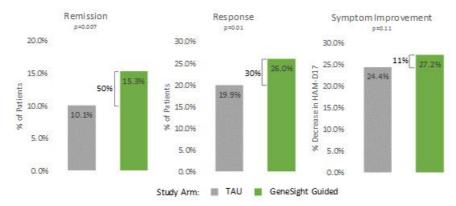
Large, Blinded Prospective Study Demonstrates that GeneSight Improves Clinical Outcomes in Patients with Treatment Resistant Major Depressive Disorder

SALT LAKE CITY, Utah, Jan. 4, 2019 – Myriad Genetics, Inc. (NASDAQ: MYGN), a global leader in personalized medicine, today announced the publication of the landmark GeneSight GUIDED study in the *Journal of Psychiatric Research*. The study is the first-ever prospective, large-scale, blinded, randomized controlled trial evaluating combinatorial pharmacogenomics testing in 1,167 patients with treatment-resistant major depressive disorder who had failed at least one psychotropic medication.

"The publication of the GUIDED study represents a major milestone for Myriad and a significant advance for pharmacogenomic testing," said Mark C. Capone, president and CEO, Myriad Genetics. "The United States has a mental health care crisis and GeneSight is a clinically proven solution to improve outcomes for patients with depression."

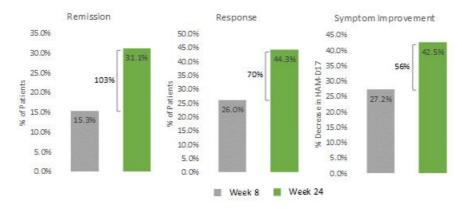
The study showed that at week 8, individuals in the GeneSight cohort had a 50 percent higher rate of remission (p=0.007), a 30 percent higher rate of response (p=0.01), and 11 percent greater improvement in symptoms (p=0.11) compared to those in the treatment-as-usual (TAU) group (Chart 1).

Chart 1: GeneSight Testing Improved Clinical Outcomes for Patients



Additionally, these results were durable and continued to improve through the 24 week follow-up period of the study, with remission rates doubling to 31 percent, response rates reaching 44 percent, and symptom improvement increasing to 43 percent (Chart 2).

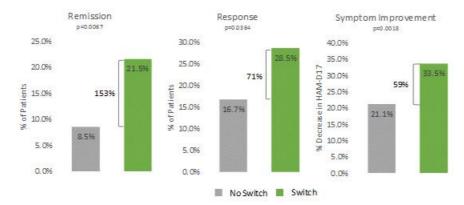
Chart 2: Durable Outcomes that Improved Through the 24 Week Follow-Up Period



Furthermore, the study demonstrated that patients have substantially better outcomes when switched from GeneSight identified 'red' category medications that were incongruent with a patient's genetic profile. A subset analysis of the patients who entered the study on red medications found that those who were switched to green or yellow category medications by week 8 had 153 percent higher rates of remission (p=0.0067), 71 percent higher rates of

response (p=0.0364), and 59 percent greater symptom improvement (p=0.0018) compared to those who remained on red category medications (Chart 3).

Chart 3: Comparison of Outcomes at Week 8 in Patients Who Entered on 'Red' Medications and Were Switched versus Patients Remaining on 'Red' Medications



"The consistently strong data supporting GeneSight when compared to an optimized active drug arm is unprecedented in depression clinical studies," said Bryan M. Dechairo, Ph.D., executive vice president of Clinical Development at Myriad Genetics. "The GUIDED study clearly demonstrates that treatment-resistant patients with major depressive disorder do better when their therapy selection is aided by GeneSight."

Investor Conference Call and Webcast

A conference call will be held today, Friday, January 4, 2019, at 4:30 p.m. ET to discuss the GUIDED publication along with the other supporting clinical evidence for GeneSight. The dial-in number for domestic callers is 1-800-670-5443. International callers may dial 1-303-223-4368. All callers will be asked to reference reservation number 21914017. An archived replay of the call will be available for seven days by dialing (800) 633-8284 and entering the reservation number above. The conference call along with a slide presentation will also will be available through a live webcast at www.myriad.com.

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 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 <u>National Institute of Mental Health</u> 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 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. Follow Myriad on Twitter via @MyriadGenetics.

Myriad, the Myriad logo, BART, BRAC*Analysis*, Colaris, Colaris AP, myPath, myRisk, Myriad myRisk, myRisk Hereditary Cancer, myChoice, myPlan, BRACAnalysis CDx, Tumor BRACAnalysis CDx, myChoice HRD, EndoPredict, Vectra, GeneSight, riskScore Prolaris,

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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 a conference call being held on Friday, January 4, 2019, at 4:30 p.m. ET, to discuss the GUIDED publication along with the other supporting clinical evidence for GeneSight; the GUIDED study demonstrating that GeneSight improves clinical outcomes in patients with treatment resistant major depressive disorder; the GUIDED study representing a major milestone for Myriad and a significant advance for pharmacogenomic testing; GeneSight being a clinically proven solution to improve outcomes for patients with depression; patients having substantially better outcomes when switched from GeneSight identified 'red' category medications that were incongruent with a patient's genetic profile; GeneSight being unprecedented in depression clinical studies when compared to an optimized active drug arm; the GUIDED study clearly demonstrating that treatment-resistant patients with major depressive disorder do better when their therapy selection is aided by GeneSight; and the Company's strategic directives under the captions "About GeneSight" and "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

over 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, Crescendo, Sividon and Counsyl; 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 most recent Annual Report on Form 10-K, 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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