Review of GeneSight® Supporting Clinical Data

January 4, 2019

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Forward Looking Statements

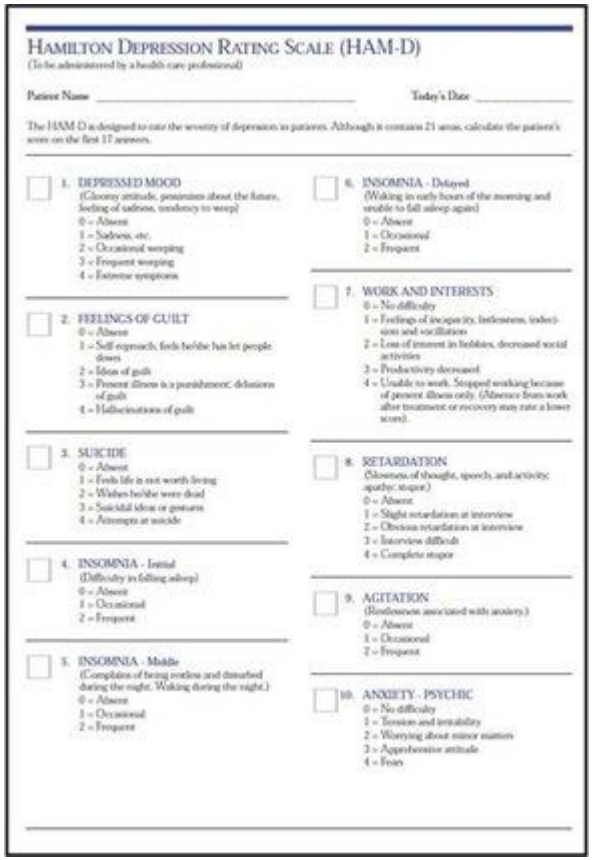
Some of the information presented here today may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company. These statements are based on management's current expectations and the actual events or results may differ materially and 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

3

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



HAMILTON DEPRESSION RATING SCALE (HAM-D)

(To be administered by a health care professional)

Patient Name _____ Today's Date _____

The HAM-D is designed to rate the severity of depression in patients. Although it contains 21 areas, calculate the patient's score on the first 17 answers.

1. DEPRESSED MOOD
(Gloomy attitude, pessimism about the future, feeling of sadness, tendency to weep)
0 = Absent
1 = Sadness, etc.
2 = Occasional weeping
3 = Frequent weeping
4 = Extreme symptoms

2. FEELINGS OF GUILT
0 = Absent
1 = Self-reproach, feels he/she has let people down
2 = Ideas of guilt
3 = Present illness is a punishment; delusions of guilt
4 = Hallucinations of guilt

3. SUICIDE
0 = Absent
1 = Feels life is not worth living
2 = Wishes he/she were dead
3 = Suicidal ideas or gestures
4 = Attempts at suicide

4. INSOMNIA - Initial
(Difficulty in falling asleep)
0 = Absent
1 = Occasional
2 = Frequent

5. INSOMNIA - Middle
(Complains of being restless and disturbed during the night. Waking during the night.)
0 = Absent
1 = Occasional
2 = Frequent

6. INSOMNIA - Delayed
(Waking in early hours of the morning and unable to fall asleep again)
0 = Absent
1 = Occasional
2 = Frequent

7. WORK AND INTERESTS
0 = No difficulty
1 = Feelings of incapacity, listlessness, indecisions and vacillation
2 = Loss of interest in hobbies, decreased social activities
3 = Productivity decreased
4 = Unable to work. Stopped working because of present illness only. (Absence from work after treatment or recovery may rate a lower score).

8. RETARDATION
(Slowness of thought, speech, and activity; apathy; stupor)
0 = Absent
1 = Slight retardation at interview
2 = Obvious retardation at interview
3 = Interview difficult
4 = Complete stupor

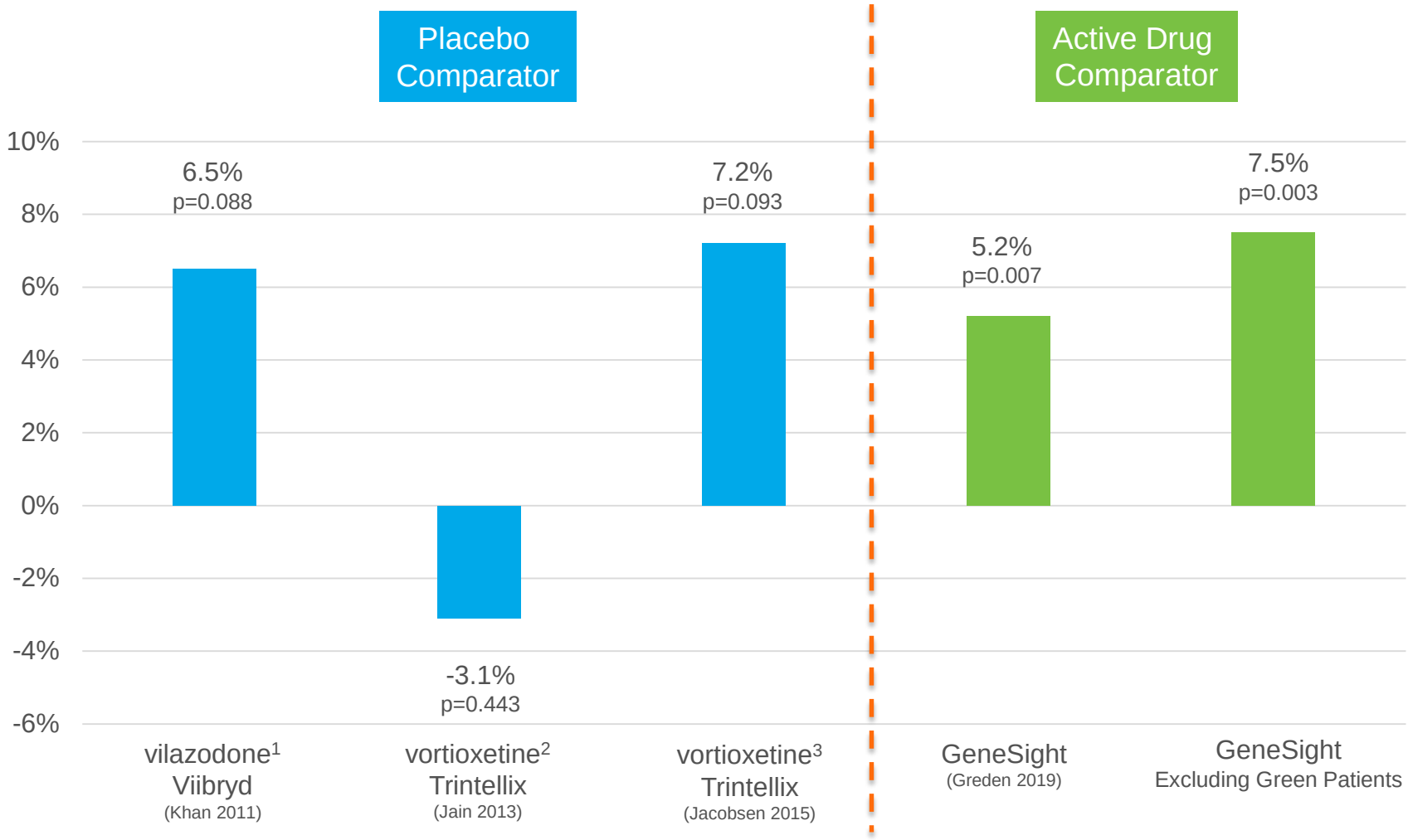
9. AGITATION
(Restlessness associated with anxiety.)
0 = Absent
1 = Occasional
2 = Frequent

10. ANXIETY - PSYCHIC
0 = No difficulty
1 = Tension and irritability
2 = Worrying about minor matters
3 = Apprehensive attitude
4 = Fears

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

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

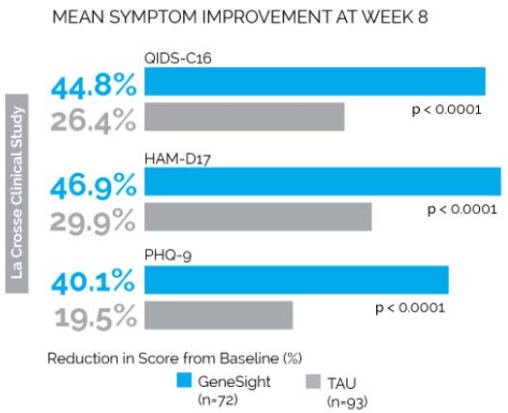
GeneSight Clinical Utility Studies Prior to GUIDED

Multiple Prior Studies Showing Clinical Utility of GeneSight

La Crosse Study
(n=165)

Key Findings:

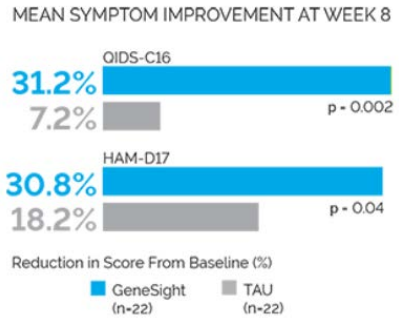
- 70% improvement in depressive symptoms (p<0.0001)
- GeneSight group 2.1x more likely to respond to medication
- Significantly higher patient satisfaction in the GeneSight arm



Hamm Study
(n=44)

Key Findings:

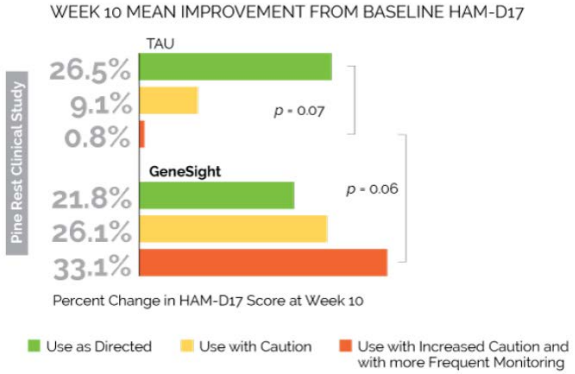
- There was a four-fold greater improvement in symptoms at week 8 in the GeneSight guided group compared to the TAU arm



Pine Rest Study
(n=49)

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

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)

National Network of Depression Centers

Perelman School of Medicine University of Pennsylvania

UT Southwestern Medical Center

Stanford Medicine

Johns Hopkins Medicine

Depression Center University of Michigan Health System

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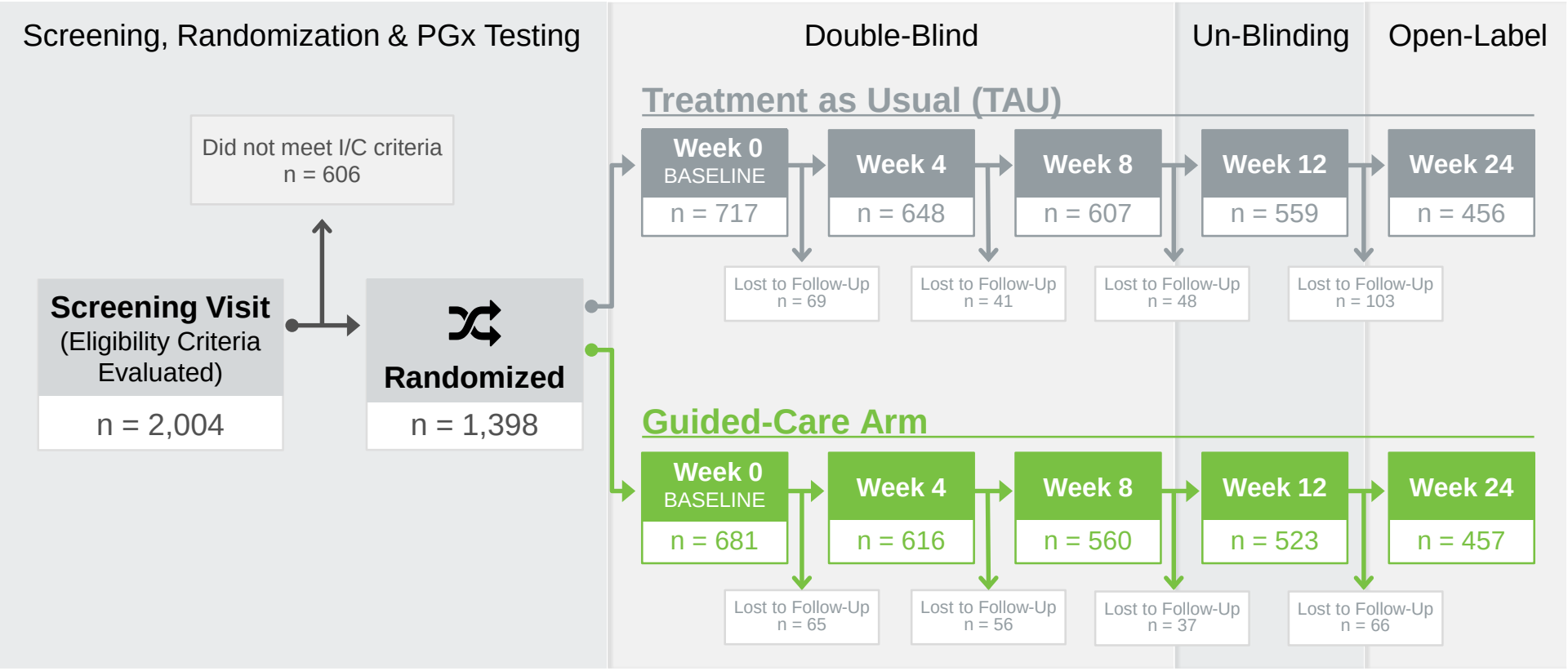
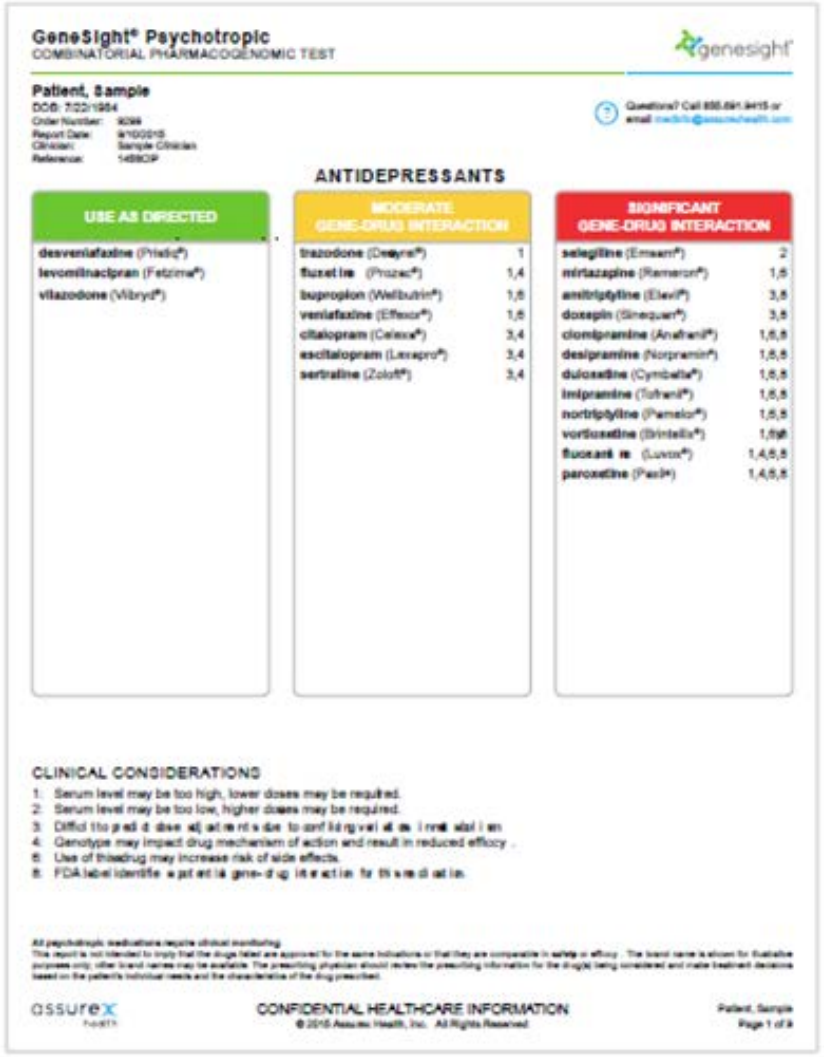
GeneSight GUIDED Study Schema



Study schema and participant enrollment in the peer-protocol cohort

GeneSight Test Report is Easy to Use and Understand



GeneSight® Psychotropic
COMBINATORIAL PHARMACOGENOMIC TEST

genesight

Patient, Sample
DOB: 7/22/1984
Order Number: 8099
Report Date: 9/10/2015
Clinician: Sample Clinician
Reference: 1488CIP

Questions? Call 855.691.9415 or email medinfo@assurehealth.com

ANTIDEPRESSANTS

USE AS DIRECTED	MODERATE GENE-DRUG INTERACTION		SIGNIFICANT GENE-DRUG INTERACTION	
desvenlafaxine (Pristiq®)	trazodone (Desyrel®)	1	selegiline (Emsam®)	2
levomilnacipran (Fetzima®)	fluoxetine (Prozac®)	1,4	mirtazapine (Remeron®)	1,5
vilazodone (Viibryd®)	bupropion (Wellbutrin®)	1,5	amitriptyline (Elavil®)	3,5
	venlafaxine (Effexor®)	1,5	doxepin (Sinequan®)	3,5
	citalopram (Celexa®)	3,4	clomipramine (Anafranil®)	1,5,5
	escitalopram (Lexapro®)	3,4	desipramine (Norpramin®)	1,5,5
	sertraline (Zoloft®)	3,4	duloxetine (Cymbalta®)	1,5,5
			imipramine (Tofranil®)	1,5,5
			nortriptyline (Pamelor®)	1,5,5
			vortioxetine (Brintellix®)	1,5,5
			fluoxetine (Luvox®)	1,4,5,5
			paroxetine (Paxil®)	1,4,5,5

CLINICAL CONSIDERATIONS

1. Serum level may be too high, lower doses may be required.
2. Serum level may be too low, higher doses may be required.
3. Difficult to predict dose adjustments due to conflicting level data. Limited data.
4. Genotype may impact drug mechanism of action and result in reduced efficacy.
5. Use of this drug may increase risk of side effects.
6. FDA label identifies potential gene-drug interaction for this medication.

All psychotropic medications require clinical monitoring.
This report is not intended to imply that the drugs listed are approved for the same indications or that they are comparable in safety or efficacy. The brand name is shown for illustrative purposes only; other brand names may be available. The prescribing physician should review the prescribing information for the drug(s) being considered and make treatment decisions based on the patient's individual needs and the characteristics of the drug prescribed.

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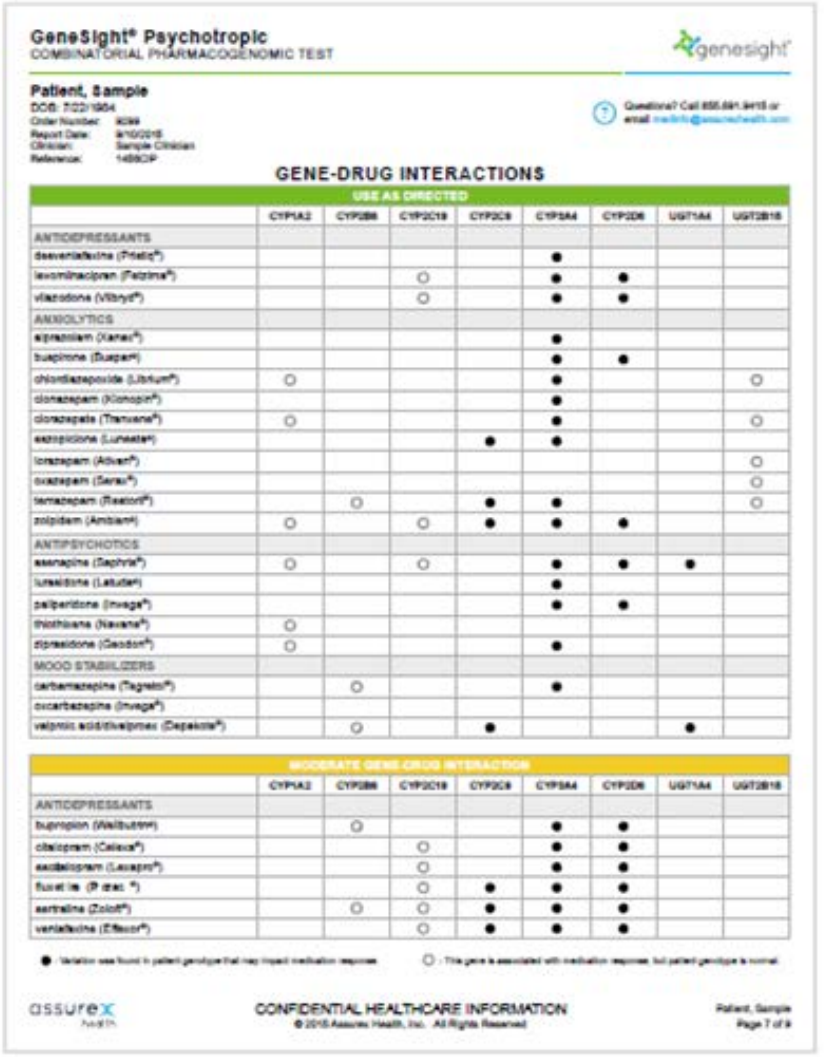

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GENE-DRUG INTERACTIONS

USE AS DIRECTED

	CYP1A2	CYP2B6	CYP2C19	CYP2C9	CYP3A4	CYP2D6	UGT1A4	UGT2B15
ANTIDEPRESSANTS								
desvenlafaxine (Pristiq®)					●			
levomilnacipran (Fetzima®)			○		●	●		
vilazodone (Viibryd®)			○		●	●		
ANXIOLYTICS								
alprazolam (Xanax®)					●			
buspirone (Buspar®)					●	●		
chlordiazepoxide (Librium®)	○				●			○
clonazepam (Klonopin®)					●			
clorazepate (Tranxene®)	○				●			○
eszopiclone (Lunesta®)				●	●			
lorazepam (Ativan®)								○
oxazepam (Serax®)								○
temazepam (Restoril®)		○		●	●			○
zolpidem (Ambien®)	○		○	●	●	●		
ANTIPSYCHOTICS								
asenapine (Saphris®)	○		○		●	●	●	
lurasidone (Latuda®)					●			
paliperidone (Invega®)					●	●		
thiothixene (Navane®)	○							
ziprasidone (Geodon®)	○				●			
MOOD STABILIZERS								
carbamazepine (Tegretol®)		○			●			
oxcarbazepine (Trileptal®)								
valproic acid/divalproex (Depakote®)		○		●			●	

MODERATE GENE-DRUG INTERACTION

	CYP1A2	CYP2B6	CYP2C19	CYP2C9	CYP3A4	CYP2D6	UGT1A4	UGT2B15
ANTIDEPRESSANTS								
bupropion (Wellbutrin®)		○			●	●		
citalopram (Celexa®)			○		●	●		
escitalopram (Lexapro®)			○		●	●		
fluoxetine (Prozac®)			○	●	●	●		
sertraline (Zoloft®)		○	○	●	●	●		
venlafaxine (Effexor®)			○	●	●	●		

● Variation was found in patient genotype that may impact medication response. ○ This gene is associated with medication response, but patient genotype is normal.

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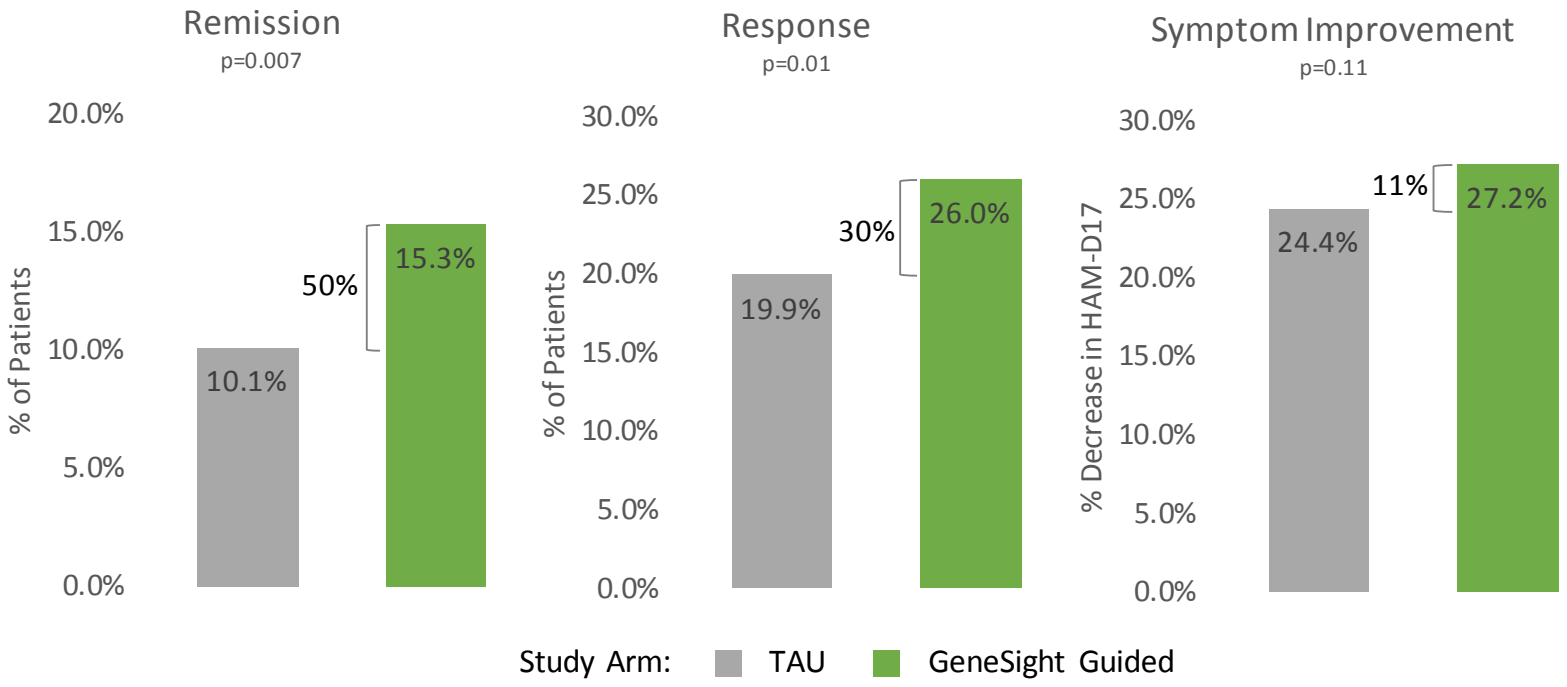
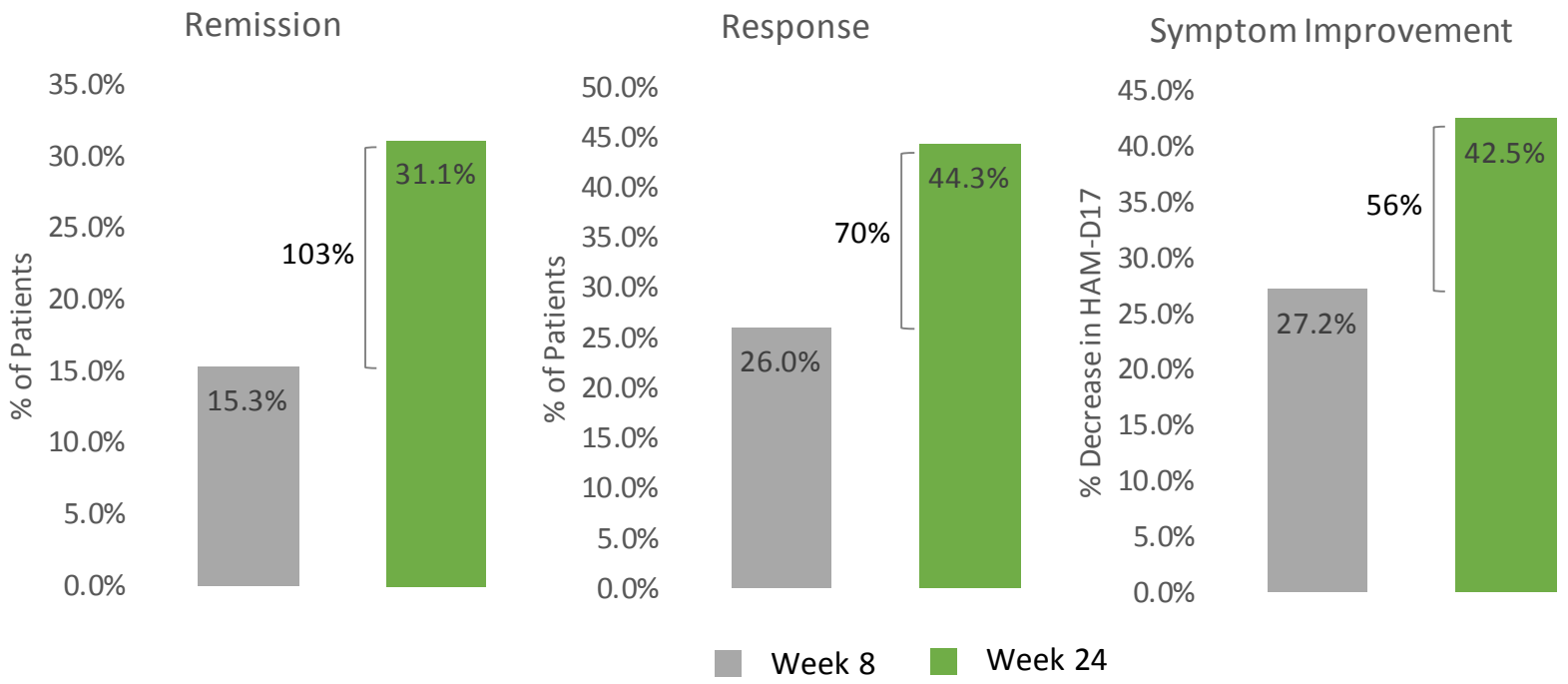
GUIDED Results Compared to Optimized Active Drug Arm

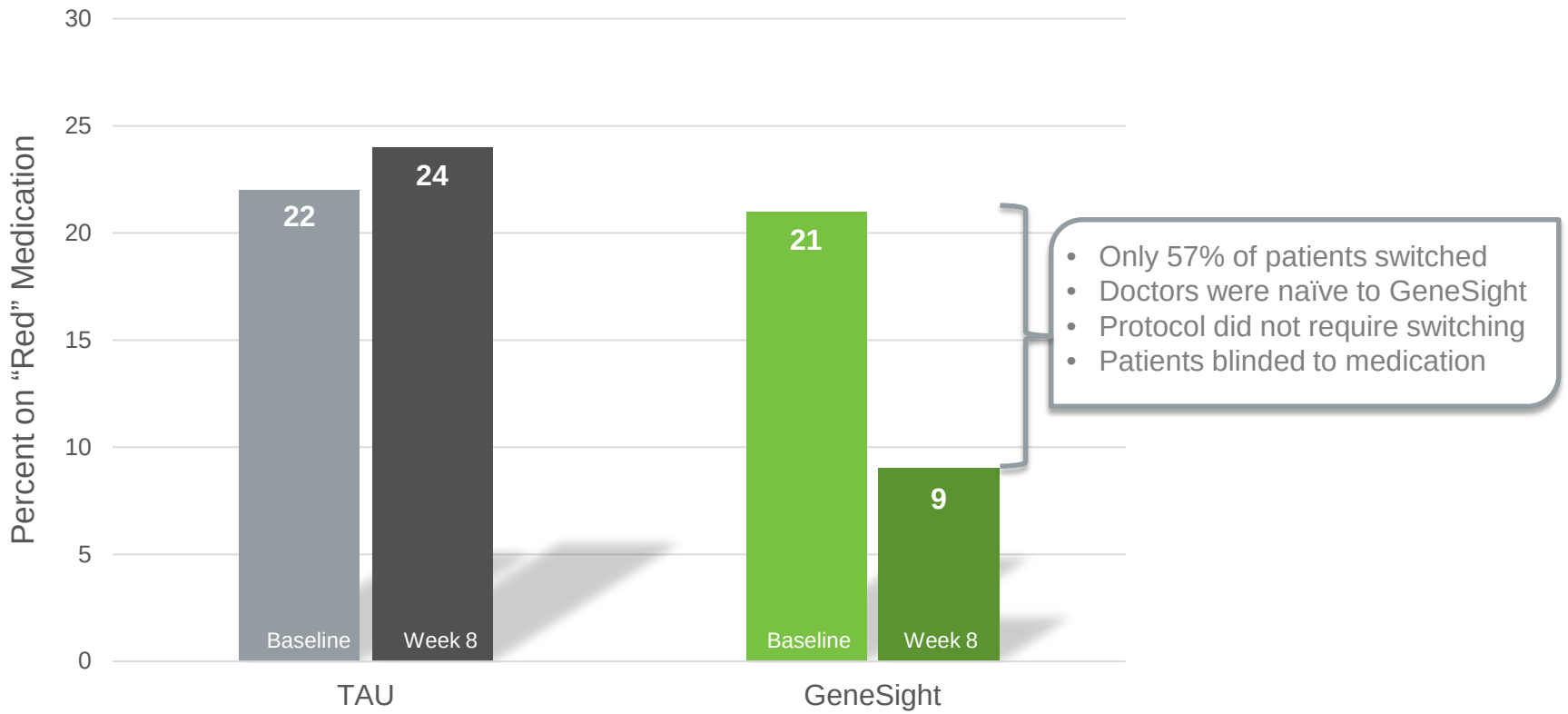


GeneSight-Driven Outcomes are Durable and Improve over 6 Months

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

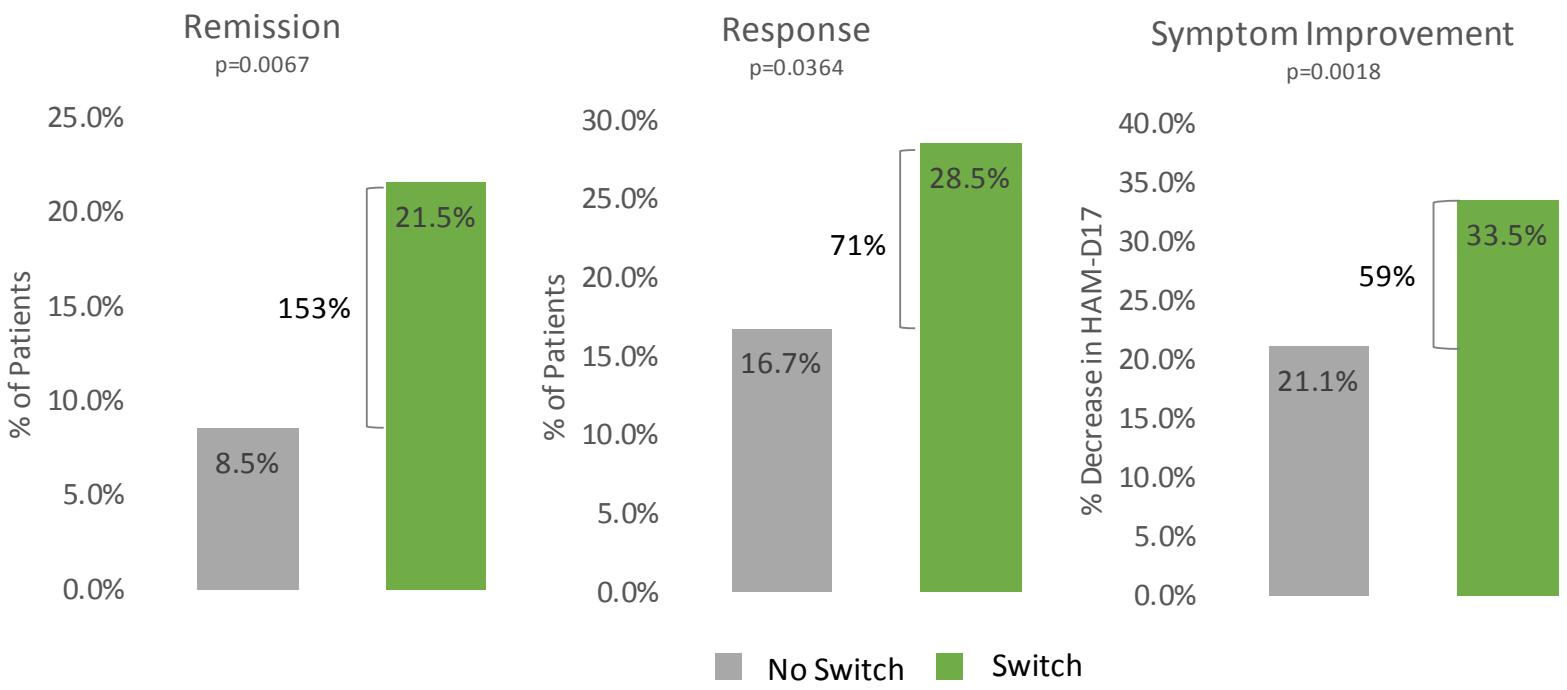


Change in “Red” Medication Use by Study Arm



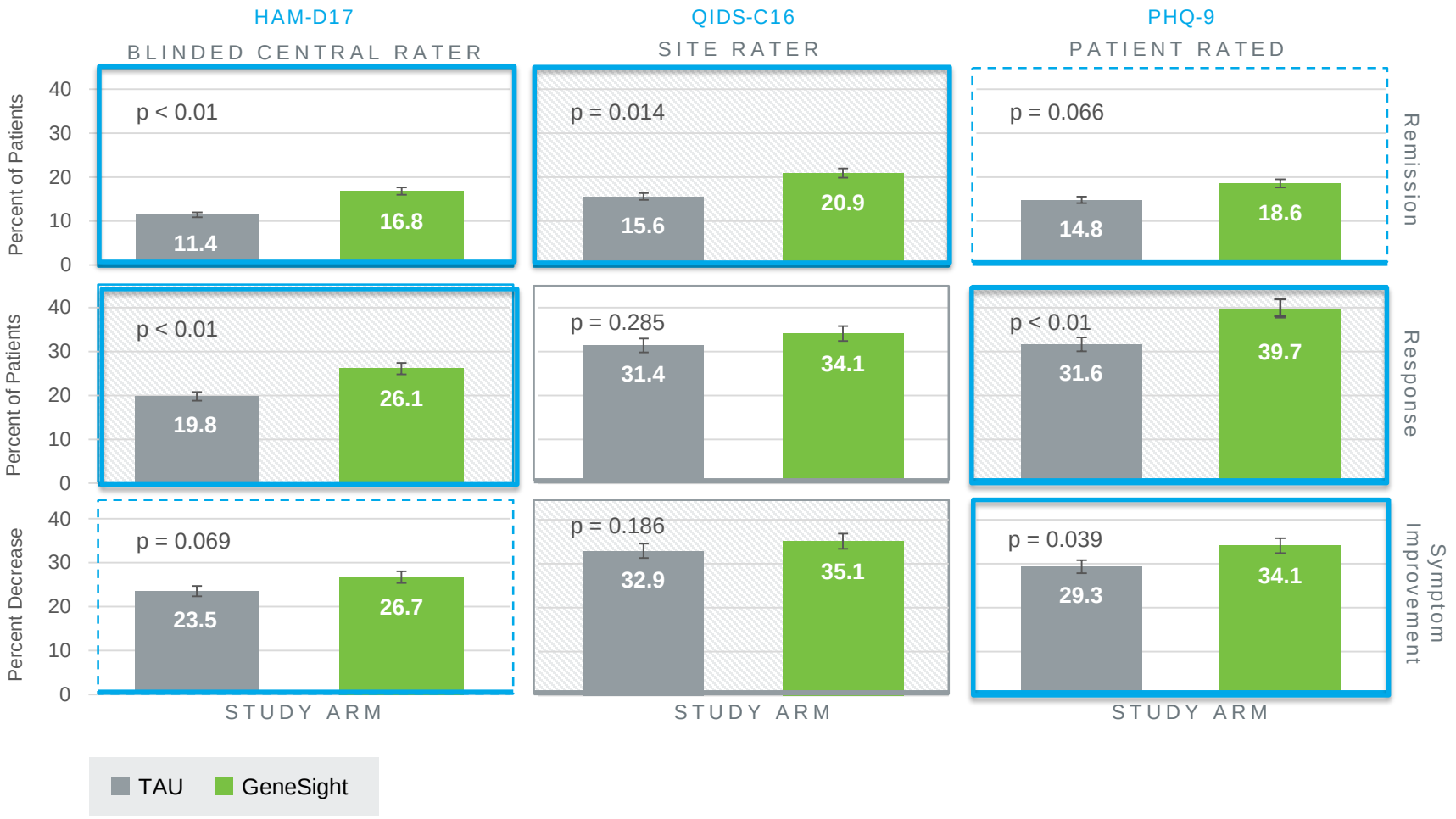
TAU physicians did not improve ending with more patients on red medications

Outcomes for Patients Switching From “Red” Medications



Endpoints for ITT* Population in 3 Depression Instruments

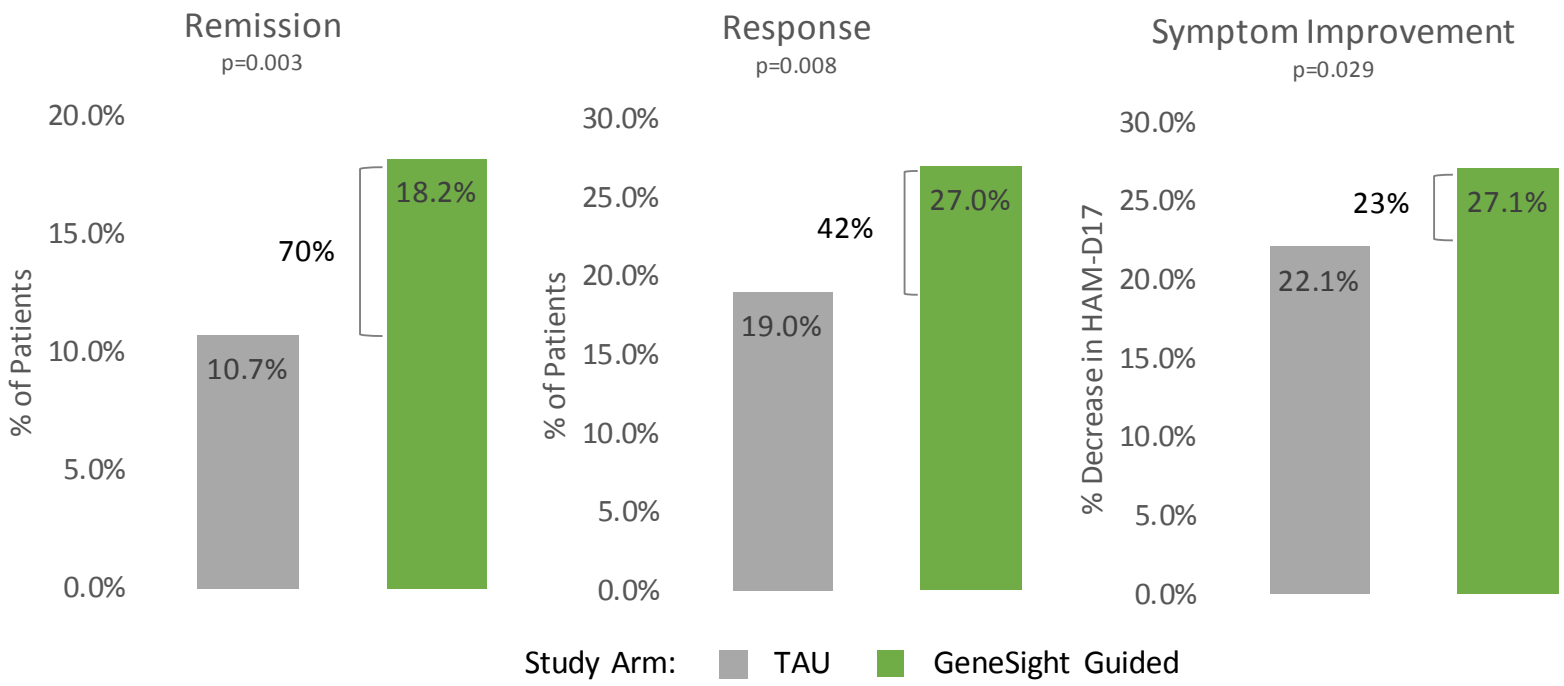
Three Endpoints Better in All Instruments and Statistically Significant In 1+ Instruments



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

IMPACT Study Results

Primary Care Physicians Had Even Better Outcomes Than Psychiatrists

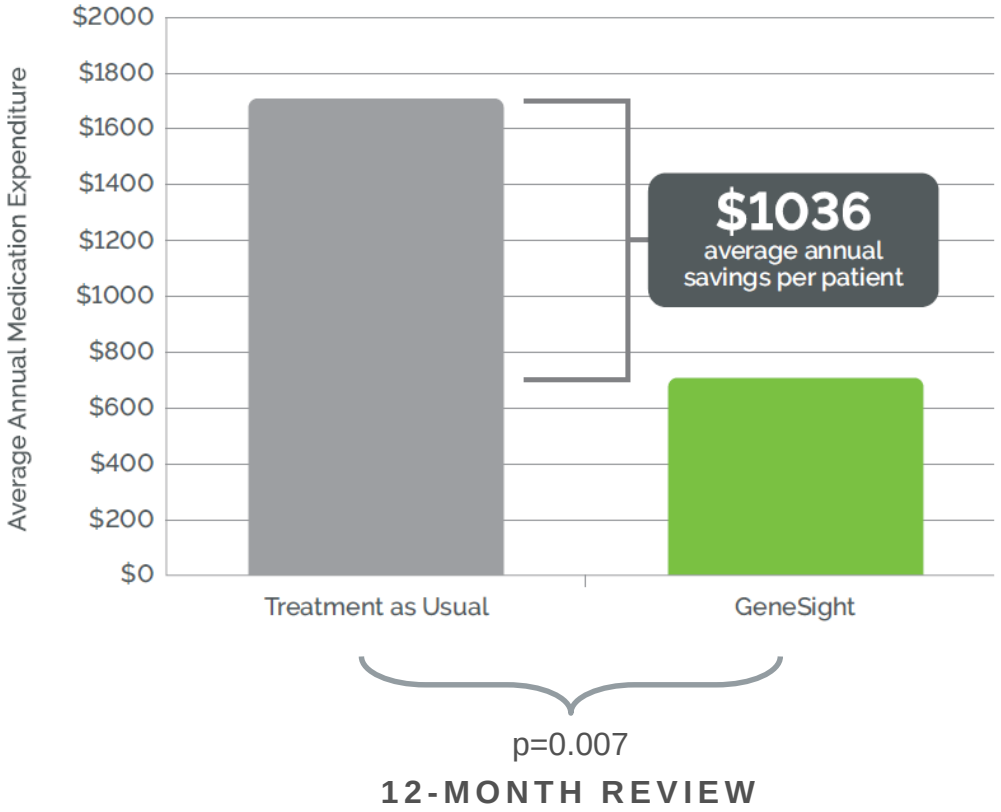
Clinical Outcome	Primary Care Physicians	Psychiatrists	% Difference	p-Value
Remission Rates	19.5%	12.0%	63%	<0.01
Response Rates	30.1%	22.3%	35%	<0.01
Symptom Improvement	31.7%	24.9%	27%	<0.01

Health Economic Data

Publication Overview

Medco Prescription Drug Study

Evaluated prescription drug claims data from 13,048 patients



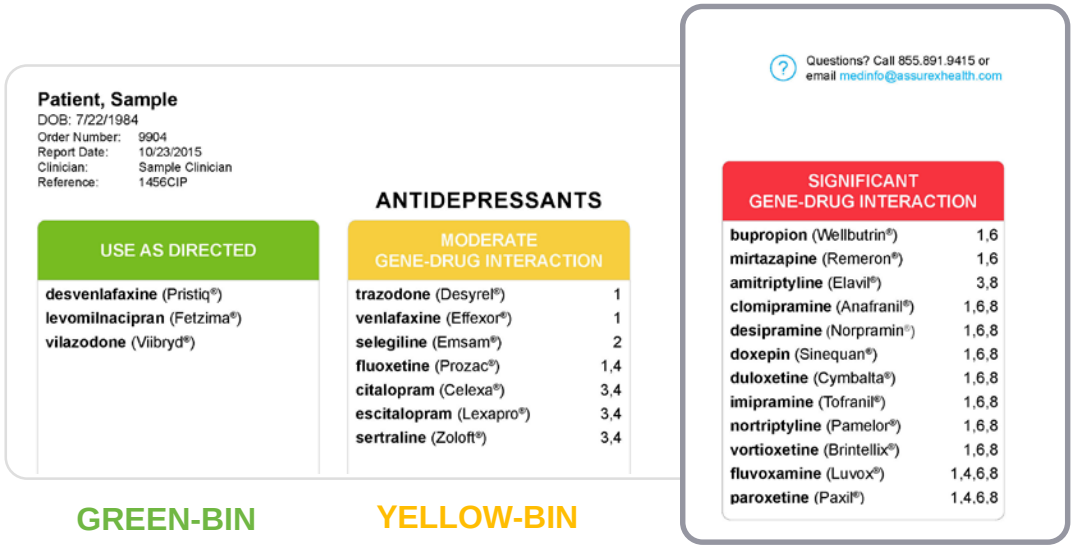
Total medication costs were reduced per patient when treatment was guided by GeneSight

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

$1,036

Drug Spend Savings[1]

+

$1,556

Healthcare Savings[2]

+

UP TO $775

Productivity Savings[2]

=

$3,367

Potential Savings Annually

Payer

Employer

1. 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)
2. 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

OPTUMInsight™

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

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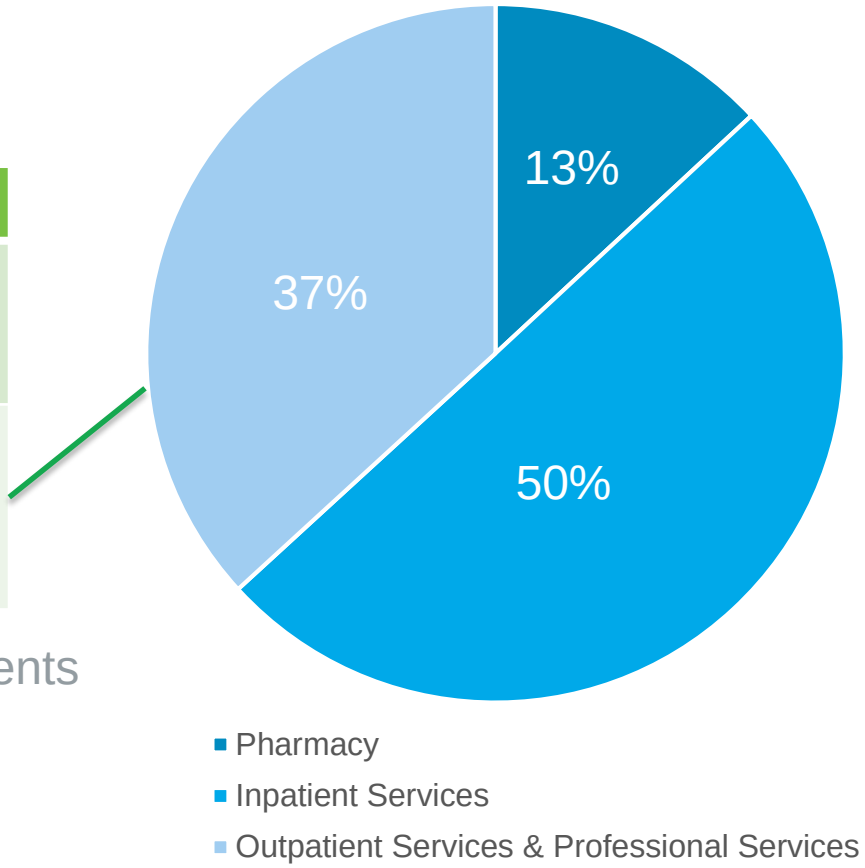
Optum Health Study Results

>$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



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