

LivaNova Education Series: Unlocking the Difficult-to-Treat Depression Opportunity

*The Road to Recovery for Patients with
Difficult-to-Treat Depression*

Intended for Investor Use Only - Not Intended for Use by Patients or HCPs

Safe Harbor

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Positioning LivaNova to Realize its Full Value

Consistently deliver growth, pipeline and profitability

Core Growth

Focus on portfolio optimization to support leadership positions in underserved markets

- Expand the go-to-market initiative for U.S. Epilepsy
- Forecast at least 20% ACS growth in 2021

Pipeline Execution

Multiple existing and pipeline initiatives to accelerate growth

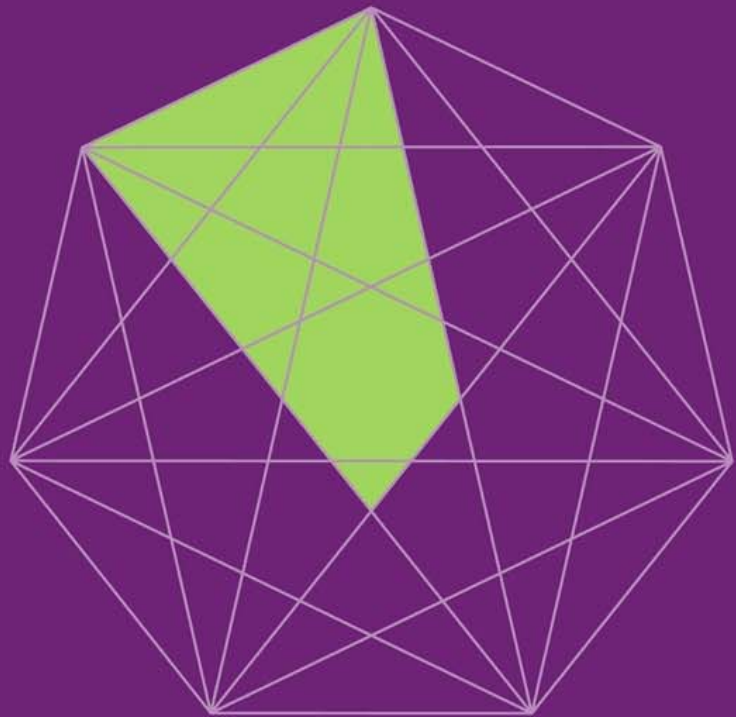
- Achieve key study milestones in RECOVER and ANTHEM HFrEF
- Continued progress on next-generation heart-lung machine

Operational Excellence

Drive margin expansion

- Expand operating margin through cost discipline
- Drive improvement in free cash flow generation





The Unmet Need in Difficult-to-Treat Depression

Jonathan Walker

U.S. General Manager & Global VP, Difficult to Treat Depression

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Depression

Depression is Common and Costly



>26 MILLION
people

are estimated to suffer with depression in the United States, **7.1% of all adults** ¹

Depression is ranked by WHO as
the single largest contributor
to global disability³

Depression is **more common among**



females (8.7%) than **males (5.3%)** ²

Veteran suicides represent 22% of all
suicide deaths in the US



An average of 20 Veterans die
by suicide each day ⁴

1. MDD Prevalence: National survey of 36,309 US adults, the 12-month prevalence of major depressive disorder were 10.4%. Hasin DS et al, Epidemiology of Adult DSM-5 Major Depressive Disorder and Its Specifiers in the United States. JAMA Psychiatry 2018;75(4):336-346.

2. <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>

3. WHO Global Health Estimates (http://www.who.int/healthinfo/global_burden_disease)

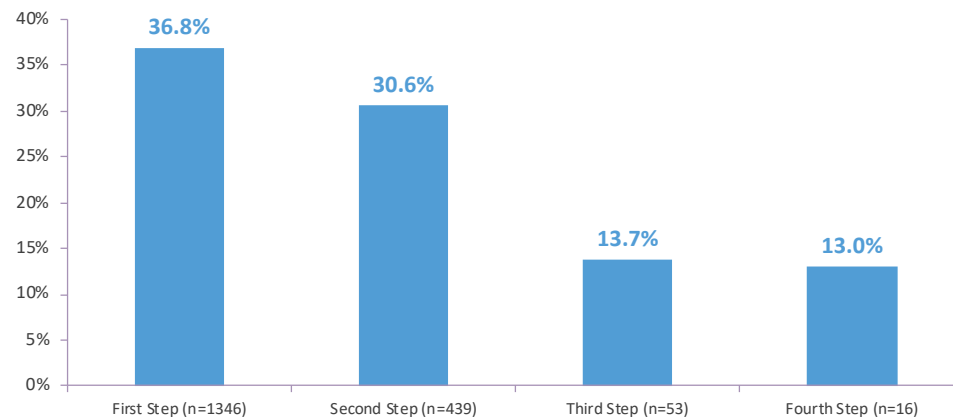
4. Department of Veterans Affairs, Office of Suicide Prevention. Suicide Among Veterans and Other Americans, 2001–2014. 3 August 2016. <https://www.mentalhealth.va.gov/docs/2016suicidedatareport.pdf>



Medication alone may not be enough for some patients

- The goal of depression treatment is to achieve a meaningful reduction in symptoms that returns patients to normal daily living
 - Response: 50% decrease in baseline index score (MADRS, HAMD, etc.)
 - Remission: minimal to no depressive symptoms
- STAR-D study demonstrates success becomes less attainable with each oral medication¹

The overall cumulative remission rate (QIDS-SR₁₆) after 4 treatment steps was **67%***



Medication alone
may not be enough
for 1 out of 3 patients



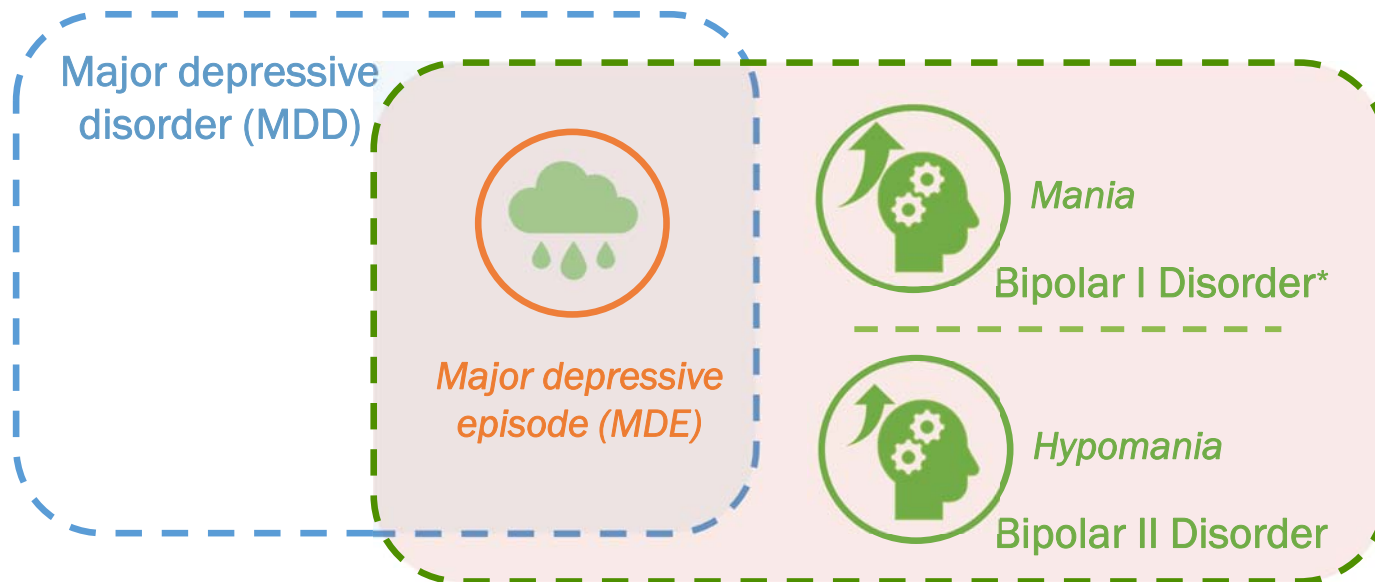
* Remission defined as QIDS-SR₁₆ score ≤ 5 at exit from the indicated treatment step. QIDS-SR: Quick Inventory of Depressive Symptomatology–Self-Report (16-item).

1. Rush AJ, Trivedi MH, Wisniewski SR, et al. Am J Psychiatry. 2006;163(11):1905–17.



DTD is not limited to MDD—it is also seen in people with Bipolar Disorder¹

Although DTD is most associated with MDD, it is also seen in the depressed phase of people with **bipolar I and bipolar II disorders**



*Bipolar I may or may not include MDE.

1. Muneer A. Korean J Fam Med. 2016;37:137–48

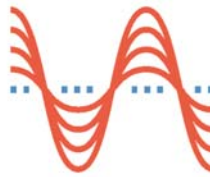


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Additional therapies are explored once patients have failed traditional pharmacological therapy^{1,2}



Psychotherapy



VNS Therapy®



*Spravato®
(esketamine)*

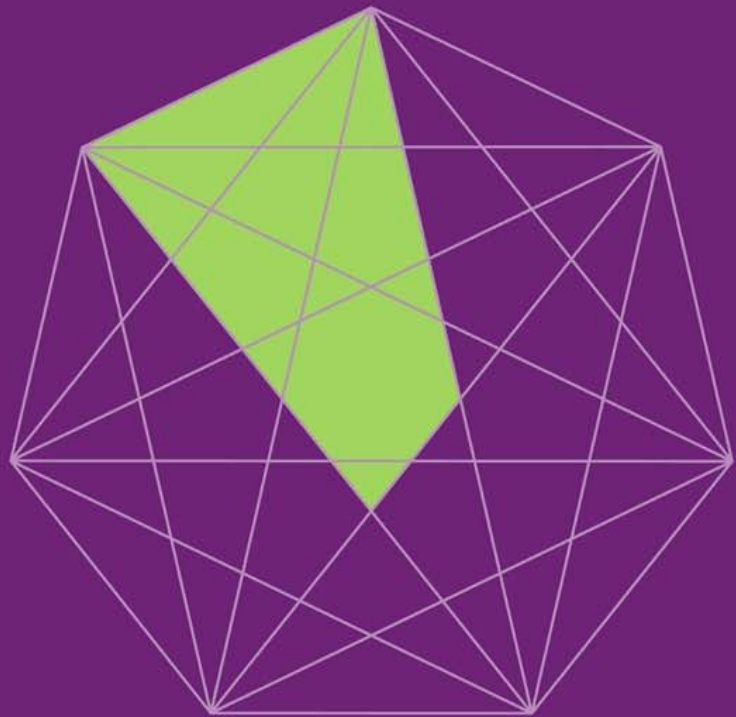


*Electroconvulsive
therapy (ECT)*



*Repetitive transcranial
magnetic stimulation
(rTMS)*

1. Al-Harbi KS. Patient Prefer Adherence. 2012;6:369–88.
2. Gelenberg AJ, et al. American Psychiatric Association. 2010



Clinical Perspectives & RECOVER Study

Dr Charles (Chuck) Conway

Professor of Psychiatry & Principal Investigator of the RECOVER Study, Washington University School of Medicine in St. Louis
St. Louis, MO

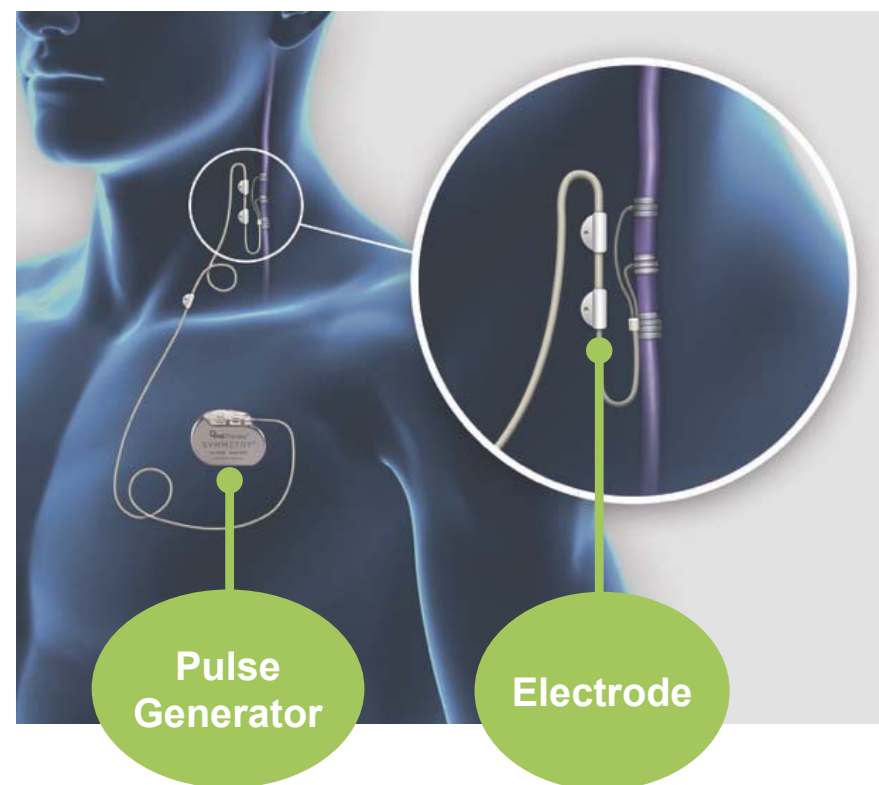
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Depression

Vagus Nerve Stimulation (VNS) Therapy®



- **VNS Therapy** is similar to a pacemaker and consists of a **small generator** and lead implanted under the skin below the collarbone
- An **attached electrode** passes stimulation to the vagus nerve, which in turn sends electrical pulses to areas of the brain associated with mood regulation¹
- Regular therapeutic delivery adjusts levels of norepinephrine, gamma-aminobutyric acid, serotonin and aspartate while also increasing blood flow to the thalamus and cortex^{1,2}
- Implant procedure takes **~1 to 2 hours** typically under **general anesthesia**³



1. Nemeroff CB, Mayberg HS, Kahl SE, et al. VNS therapy in treatment-resistant depression: clinical evidence and putative neurobiological mechanisms. *Neuropsychopharmacology*. 2006;31(7):1345-1355.

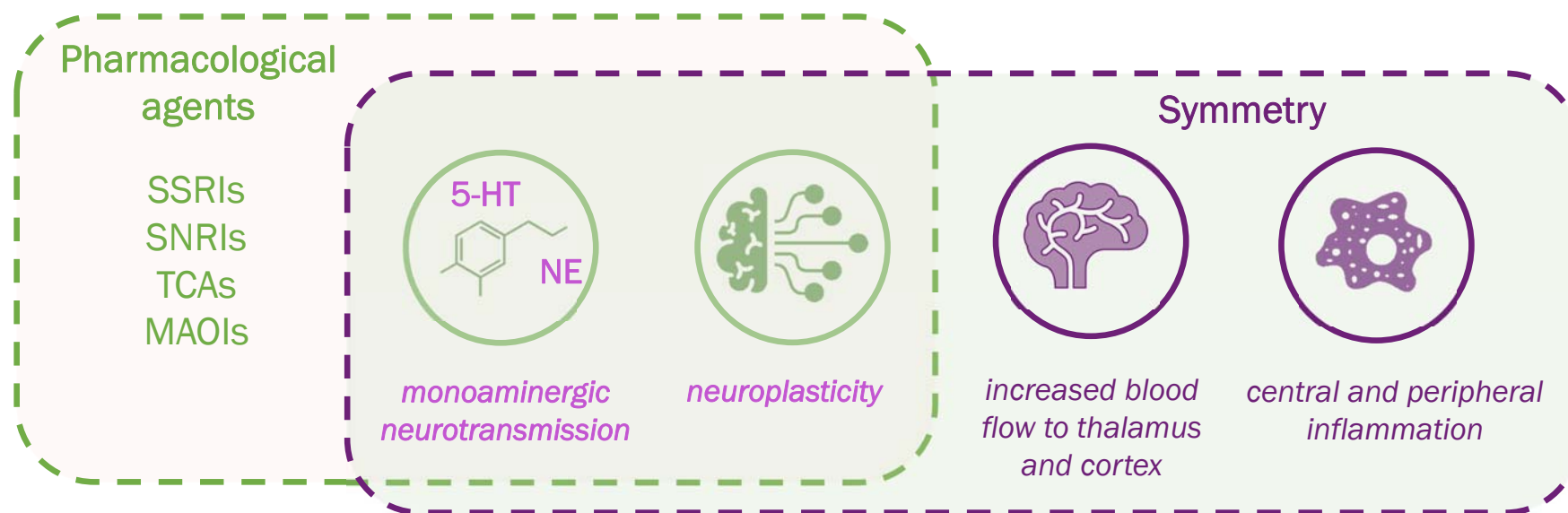
2. Henry TR, Bakay RAE, Votaw JR, et al. Brain blood flow alterations induced by therapeutic vagus nerve stimulation in partial epilepsy: I. Acute effects at high and low levels of stimulation. *Epilepsia*. 1998;39(9):983-990.

3. LivaNova VNS Therapy® System Depression Physician's Manual, May 2020.



VNS Therapy[®] modulates established pathways involved in depression^{1,2,3}

Treatment targets



SSRI: selective serotonin reuptake inhibitor; SNRI: serotonin-norepinephrine reuptake inhibitor; TCA: tricyclic antidepressant; MAOI: monoamine oxidase inhibitor; 5-HT: serotonin; NE: norepinephrine.

1. Nemeroff CB, Mayberg HS, Kahl SE, et al. Neuropsychopharmacology. 2006;31:1345–55. 2. Henry TR, Bakey RAE, Votaw JR, et al. Epilepsia. 1998;39(9):983–90. 3. Ondicova K, Pecanek J, Mravec B. Neuroendocrinol Lett. 2010;31.



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Pivotal studies leading to FDA approval in 2005

Study Number	Study Design	# Patients	HAMD Response Rate	
			TAU	VNS + TAU
D-01 Pilot Study ¹	12 week open-label feasibility	60	N/A	15%
D-02 Acute Pivotal Study ²	10 week double-blind, randomized, sham treatment- controlled	235 enrolled and implanted; 222 evaluable	10%	15% (p=0.251)
D-02 Long-Term Pivotal Study ³	12 months open-label long-term follow up	233 entered long-term; 205 evaluable	N/A	27%
D-04 Comparative Study ⁴	12 months observational study of standard-of-care therapies in TRD patient for comparison with pivotal study D02	127 enrolled; 124 evaluable	13%	N/A

1. Rush, et al. Biol Psychiatry 2000; 47:276-286, 2. Rush AJ et al. Biol Psychiatry 2005;58:347-54, 3. Rush AJ, et al. Biol Psychiatry. 2005;58:355-363, 4. George MS, et al. Biol Psychiatry. 2005;58:364-373



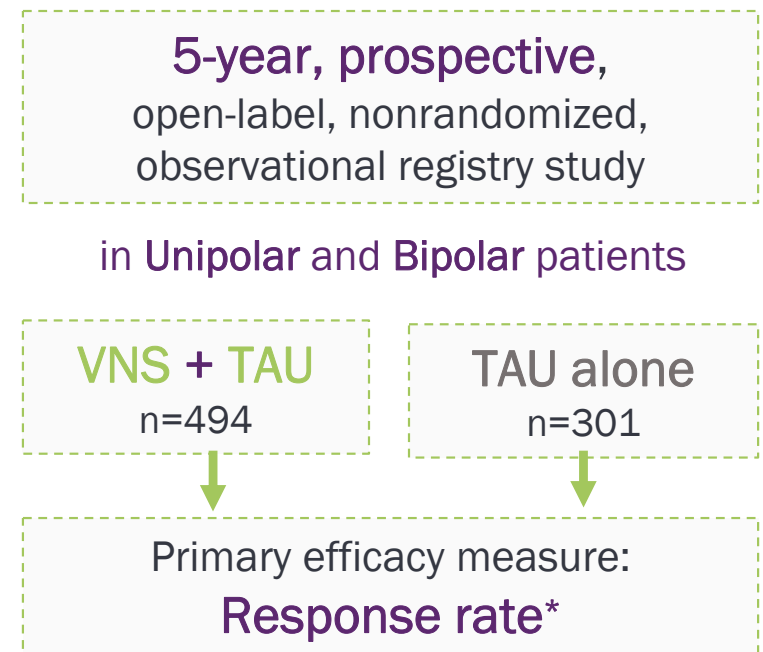
D23 5-year long-term safety and efficacy data for VNS Therapy® in TRD was published in the *American Journal of Psychiatry* ¹

ARTICLES

A 5-Year Observational Study of Patients With Treatment-Resistant Depression Treated With Vagus Nerve Stimulation or Treatment as Usual (TAU): Comparison of Response, Remission, and Suicidality

Scott T. Aaronson, M.D., Peter Sears, C.C.R.P., Francis Ruvuna, Ph.D., et al.

i **Treatment-as-usual (TAU)** includes standard-of-care psychotropic medications and non-pharmacologic treatments, such as psychotherapy, cognitive behavioral therapy and electroconvulsive therapy (ECT)^{1,2}



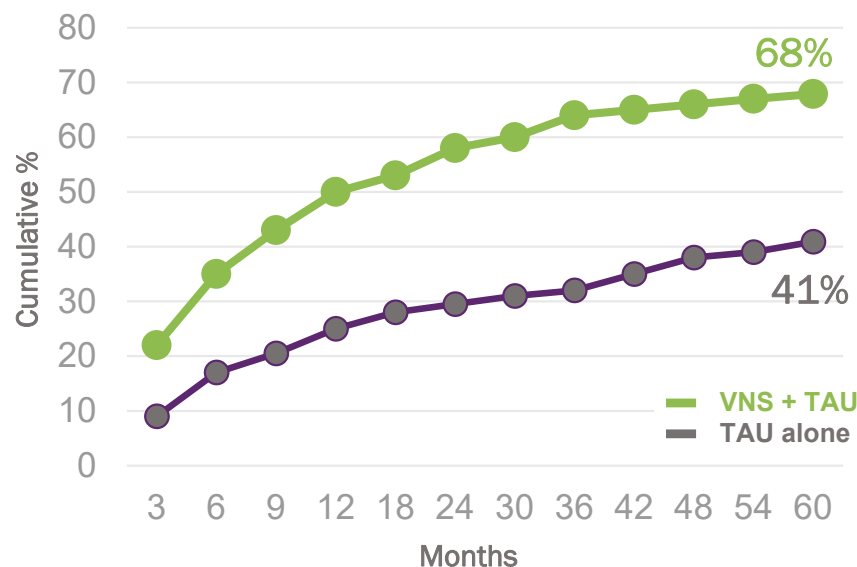
*Response rate defined as decrease of ≥50% from baseline in MADRS score at any post-baseline visit during the study. MADRS: Montgomery-Åsberg Depression Rating Scale.

1. Aaronson ST, Sears P, Ruvana F, et al. *Am J Psychiatry*. 2017;174:640-48.

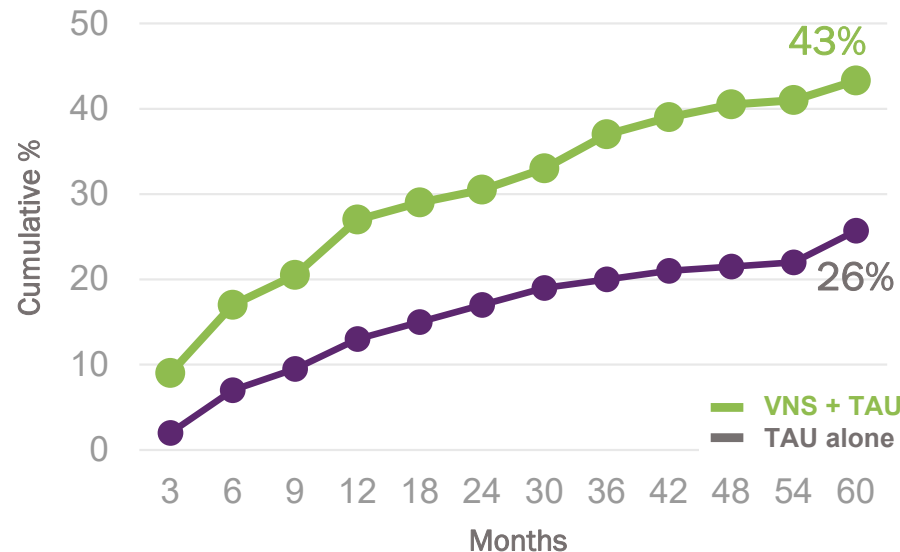
2. LivaNova VNS Therapy® System Depression Physician's Manual, May 2020

VNS Therapy® + TAU delivered superior response and remission rates vs TAU alone over 5 years

Significantly higher 5-year cumulative response rate* ($P < 0.001$)¹



Significantly higher 5-year cumulative remission rate** ($P < 0.001$)¹



Efficacy analysis conducted on intent-to-treat population. *Response rate defined as decrease of $\geq 50\%$ from baseline in MADRS score at any post-baseline visit during the study. **Remission based on MADRS score ≤ 9 at a post-baseline visit, a QIDS-SR score ≤ 5 at a post-baseline visit, and a CGI-I score of 1 at a post-baseline visit. ITT population was used for efficacy analysis.

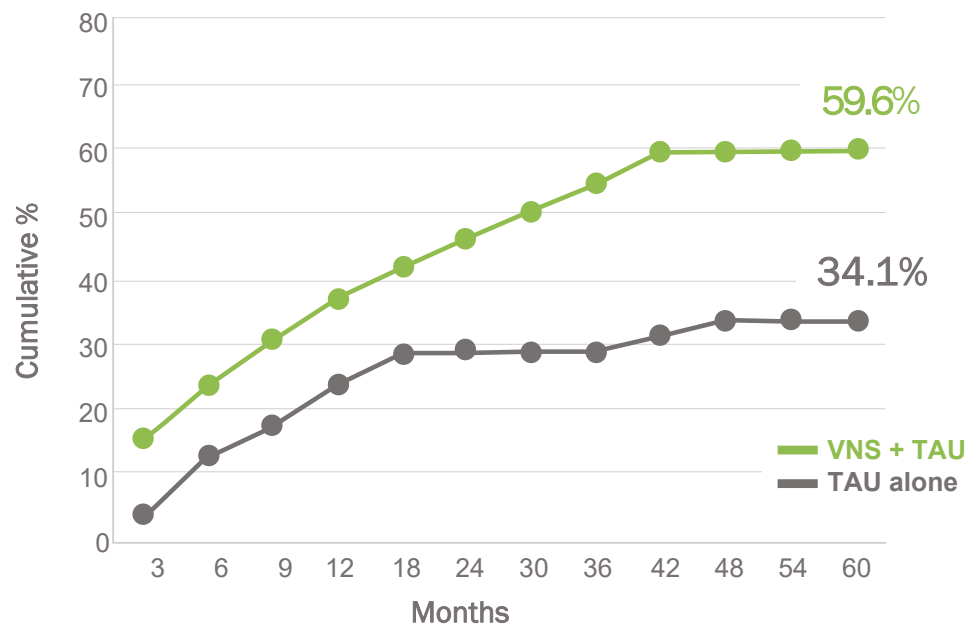
1. Aaronson ST, Sears P, Ruvana F, et al. *Am J Psychiatry*. 2017;174:640-48.



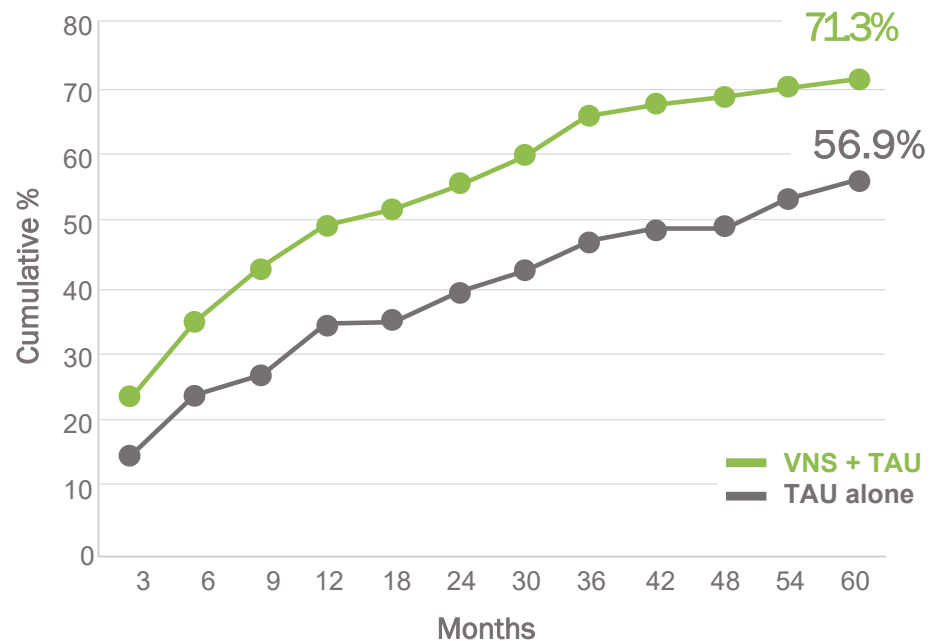
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More patients responded to VNS Therapy® + TAU regardless of success with prior ECT therapy¹

5-year cumulative response rate,
history of **ECT Non-responders** ($P < 0.001$)



5-year cumulative response rate,
history of **ECT Responders** ($P < 0.006$)

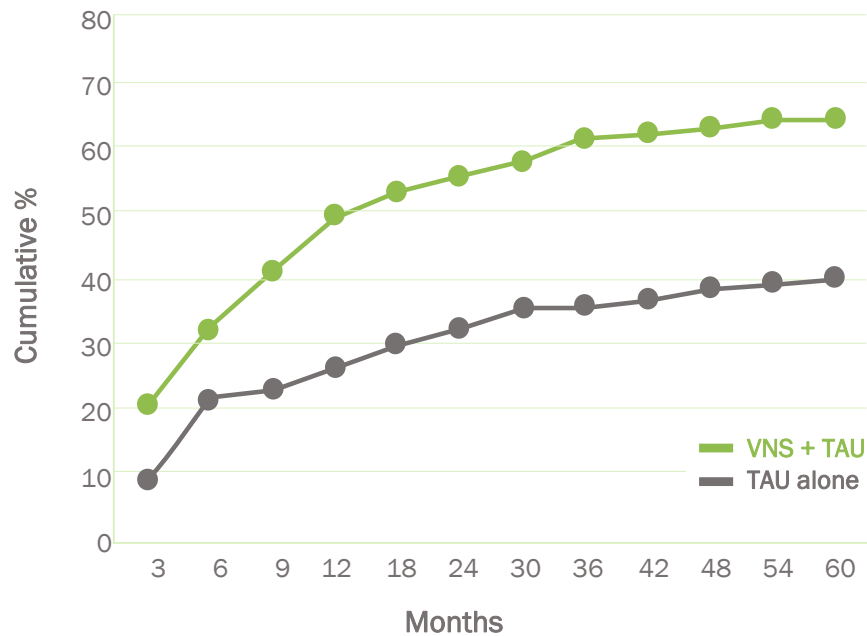


1. Aaronson ST, Sears P, Ruvana F, et al. *Am J Psychiatry*. 2017;174:640-48.

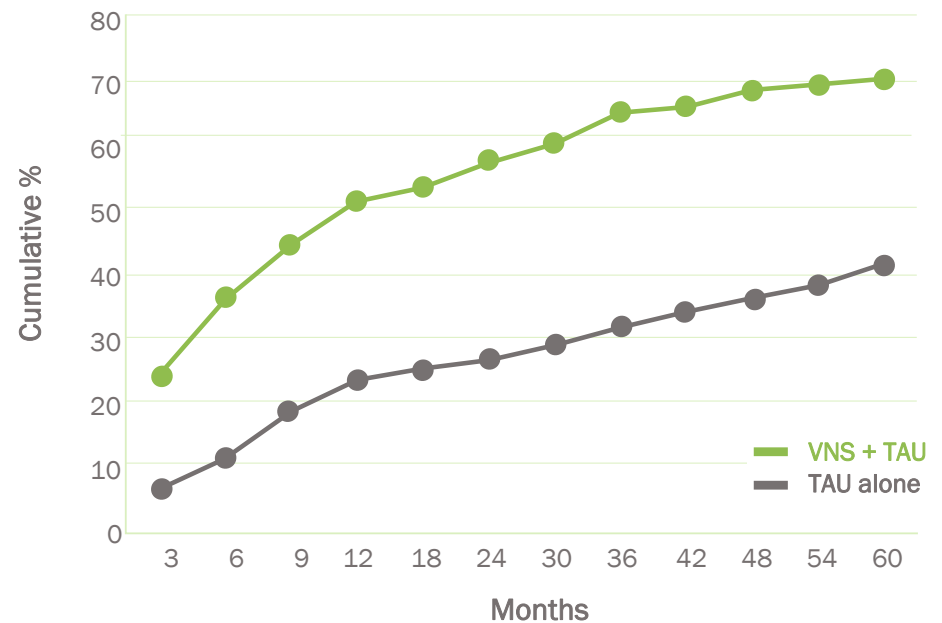


Patients with comorbid, underlying anxiety benefit from VNS Therapy® + TAU¹

5-year cumulative response rate,
Baseline Anxiety ($P < 0.001$)



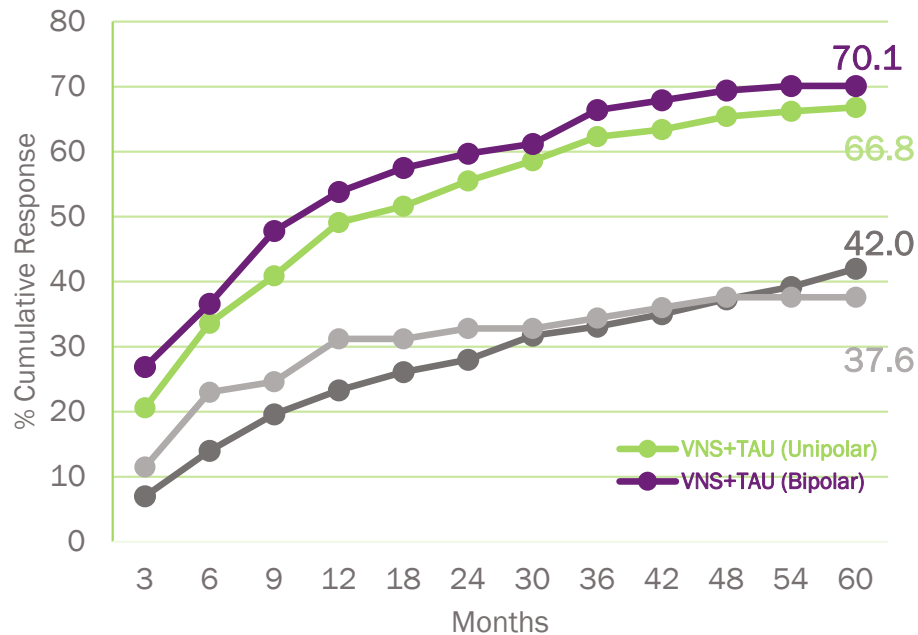
5-year cumulative response rate,
No Baseline Anxiety ($P < 0.006$)



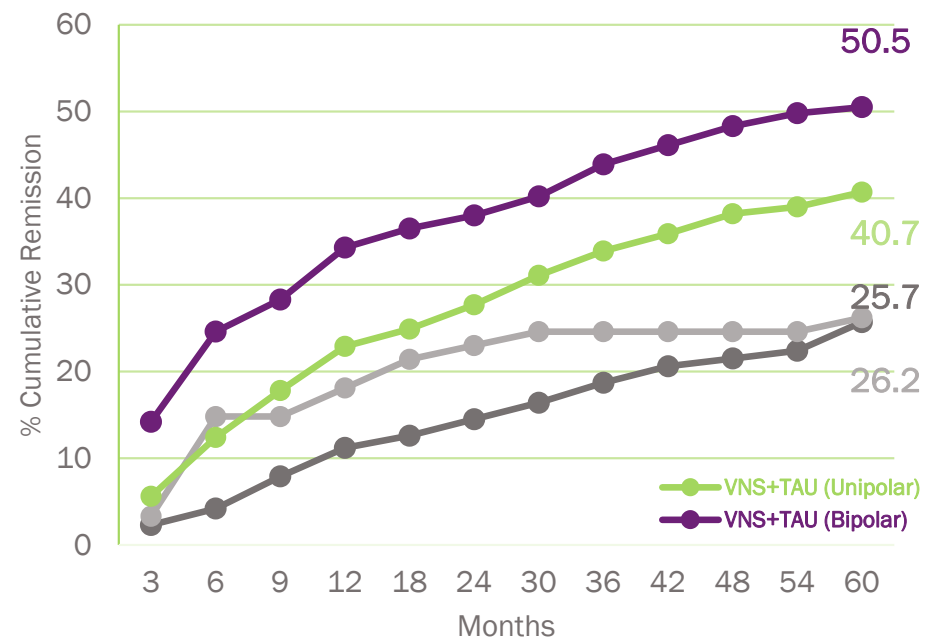
1. Aaronson ST, Sears P, Ruvana F, et al. *Am J Psychiatry*. 2017;174:640-48.

Patients with Bipolar or Unipolar Depression benefit from VNS Therapy® + TAU¹

Cumulative First-Time Response Rate (p<0.05)



Cumulative First-Time Remission Rate (p<0.05)

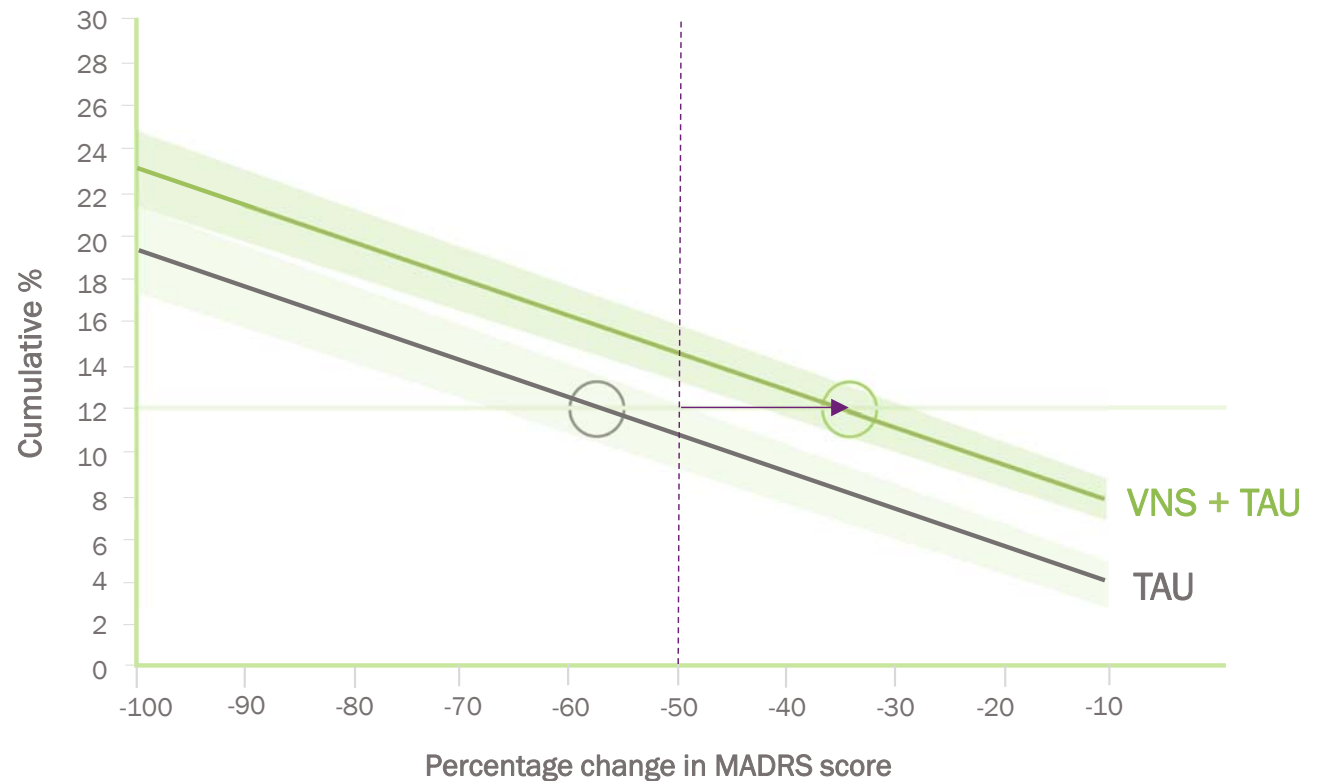


1. McAllister-Williams RH et al. The effects of vagus nerve stimulation on the course and outcomes of patients with bipolar disorder in a treatment-resistant depressive episode: a 5-year prospective registry. Int J Bipolar Disord (2020) 8:13.

Significant, sustained quality of life (QoL) with VNS Therapy® + TAU¹

Patients receiving VNS Therapy had a clinically meaningful QoL improvement well before the classically defined antidepressant response* was reached

*50% reduction in MADRS



1. Conway CR, Kumar A, Xiong W, et al. Chronic vagus nerve stimulation significantly improves quality of life in treatment-resistant major depression. J Clin Psychiatry. 2018;79(5):18m12178..



All cause mortality and suicidality improved with VNS Therapy® + TAU ¹

Measure	VNS Group (n=494)	TAU Group (n=301)
Number of deaths during study participation	7	8
Exposure (patient-years)	1985	926
All cause mortality per 1,000 patient years	3.53	8.63
Number of suicides during study participation	2	2
Suicides per 1,000 patient years	1.01	2.20

1. Aaronson ST, Sears P, Ruvana F, et al. *Am J Psychiatry*. 2017;174:640-48.

VNS Therapy® has a well-tolerated, non-pharmacologic side effect profile, which was less noticeable over time^{1,2}

Implant and stimulation-related adverse events reported in $\geq 5\%$ of patients are listed in order of decreasing occurrence:^{1,2}

- Common implant issues include incision pain, voice alteration, incision site reaction, device site pain, device site reaction, pharyngitis, dysphagia, hypesthesia, dyspnea, nausea, headache and neck pain
- Common stimulation issues include hoarseness/changes in voice tone, prickly feeling in the skin, shortness of breath, sore throat and coughing. These generally only occur during stimulation and were less noticeable over time

Adding VNS Therapy does not impart a clinically greater side-effect burden than what is seen with traditional treatment alone, based on patient self-assessments

1. LivaNova VNS Therapy® System Depression Physician's Manual, May 2020.
2. Berry SM, Broglio K, Bunker M, et al. *Med Devices (Aukl)*. 2013;6:17–35.

VNS Therapy® demonstrates a unique profile of therapeutic benefits

Long-term efficacy



Sustained efficacy that increases over time, with therapeutic benefits to 5 years following implantation¹

Quality of life



Significant improvements in quality of life, including mood and overall well-being²

Suicidality



Significantly greater reduction in suicidality compared to TAU alone¹

Assured treatment delivery with no additional pill burden^{3*}

*Because VNS Therapy is not an oral treatment, it does not result in an increase in a patient's pill burden. TAU: treatment-as-usual.

1. Aaronson ST, Sears P, Ruvana F, et al. Am J Psychiatry. 2017;174:640-48. 2. Conway CR, Kumar A, Xiong W, et al. J Clin Psychiatry. 2018;79:18m12178.

3. O'Reardon JP, Cristancho P, Peshek AD. Psychiatry. 2006;3(5):54-63.



A woman with long brown hair, seen from behind, is looking out a large window. Outside, three people are sitting at a small round table in a lush garden. The garden has green grass, various plants, and trees in the background. The scene is bright and sunny.

RECOVER Trial Overview



RECOVER
A VNS Therapy® Clinical Trial

History

2005

VNS Therapy approved to treat subjects with TRD by FDA

Coverage determined by local Medicare Administrative ContractorS (MACS)

2006

Formal request for NCD to include coverage of VNS for TRD

2007

CMS determined VNS for TRD non-covered: CMS concluded that VNS was not reasonable and necessary for TRD

2018

Formal request to reconsider NCD to remove non-coverage of VNS Therapy for TRD

2019

RECOVER protocol agreed with CMS & 1st patient implanted (Sept)

The RECOVER Study: Overview¹

Clinical Study Objective

Compare VNS Therapy® vs No Stimulation control in subjects with treatment-resistant depression (TRD)

Rate of MADRS Response

- 1) Defined as total # of months in response divided by total months of expected study participation
- 2) 50% reduction in baseline MADRS total score at 12 Months

Prospective

Multi-Center

Blinded

RCT

Primary End Point

MADRS Rate of Response
(defined as reduction of 50% vs baseline)

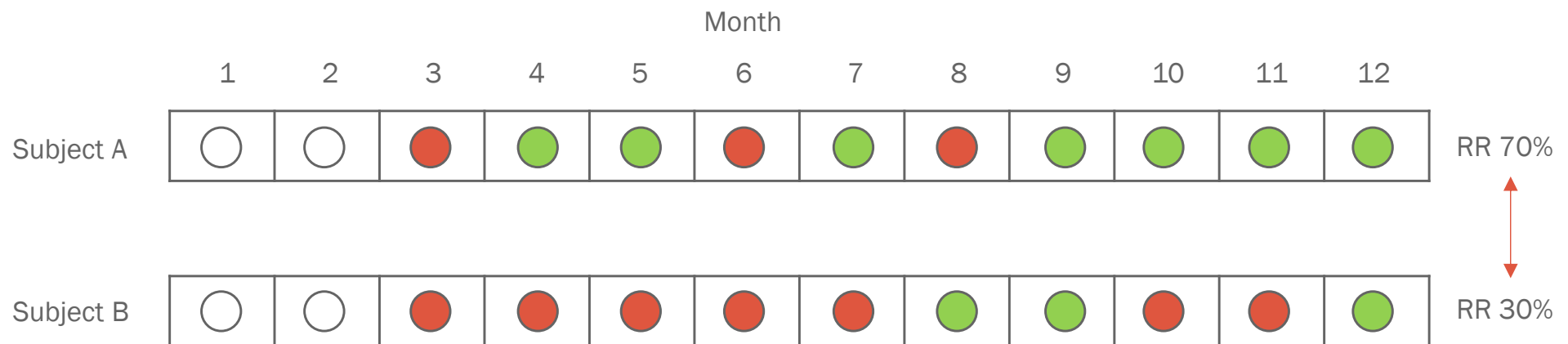
Study Size and Analysis Plan

- 1) RCT Phase up to 1,000 patients
- 2) Longitudinal Registry Phase up to 5,800 patients
- 3) Medicare participants reimbursed by CMS
- 4) Incorporate adaptive design
- 5) First interim analysis triggered by achieving 250 implanted unipolar and/or 150 bipolar patients

1. Conway CR. et al. *Contemporary Clinical Trials* 95 (2020).

MADRS Rate of Response (Illustrative Example Only)

Rate of Response shows how many patients respond and how often they are in response in one endpoint



● $\geq 50\%$ reduction in MADRS in that month, from average of BL1 & BL2 score

● $< 50\%$ reduction in MADRS in that month, from average of BL1 & BL2 score

○ Patient in titration period, no evaluation

Data Requirements for Registry Transition vs NCD Consideration

Submitted for transition to registry	Submitted for NCD consideration
<ul style="list-style-type: none"> Rate of MADRS response 	<ul style="list-style-type: none"> Rate of MADRS response Rate of MADRS remission Time to first MADRS response Time to first MADRS remission Maximum duration of MADRS response Maximum duration of MADRS remission Disability: Changes in score of WHODAS Quality of life: Change in percent maximum score from baseline scores in Q-LES-Q-SF Psychiatric status: Rate of CGI-I response Suicidality: Items #6 and #8 of S-STS Relationship of rate of MADRS response to baseline demographics, medical history, psychiatric comorbidities, and baseline levels of other variates of interest Adverse events, device deficiencies, all-cause mortality

- There are other exploratory endpoints to support the assessment of efficacy and safety of VNS in TRD population
- Longitudinal Registry endpoints will be the same of the RCT

The RECOVER Study: Patient selection ¹

Key inclusion criteria

- 18 years or older
- Documented diagnosis of MDD or Bipolar Depression: either chronic (≥ 2 years) or recurrent (≥ 4 prior episodes, at least two months apart) according to DSM-5
- Insufficient response to ≥ 4 adequate trials of antidepressant treatment in the current episode (any combination of the following: oral depressant drugs of different classes, psychotherapy, repetitive transcranial magnetic stimulation (rTMS) and ECT)
- Score of at least 22 on both baseline administrations of the Montgomery-Åsberg Depression Rating Scale (MADRS), with a difference between the two scores that does not exceed 25%
- Continued use of mood stabilizer if bipolar

Key exclusion criteria

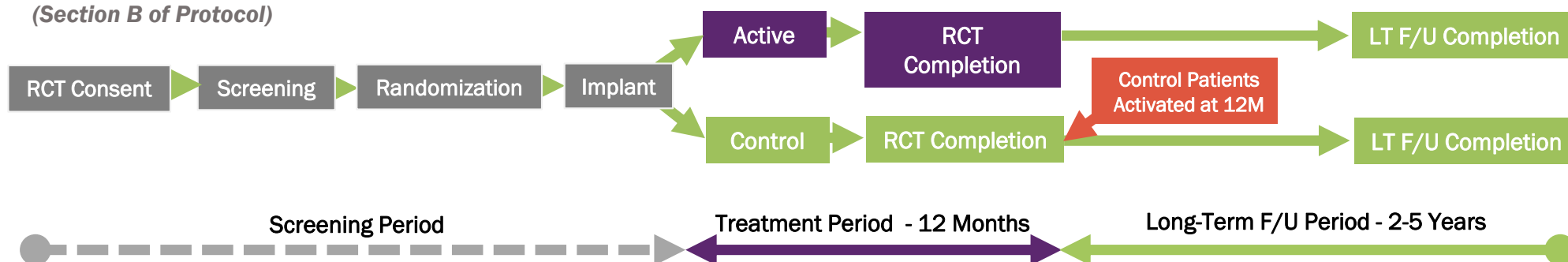
- Acute suicidality or recent suicide attempt
- History of substance abuse (past 12 months)
- History of psychosis
- Severe personality disorder
- Deep brain stimulation implant
- Dementia

1. Conway CR. et al. *Contemporary Clinical Trials* 95 (2020).

The RECOVER Study: Design - RCT and Registry Phase¹

RCT + Follow-up Study

(Section B of Protocol)

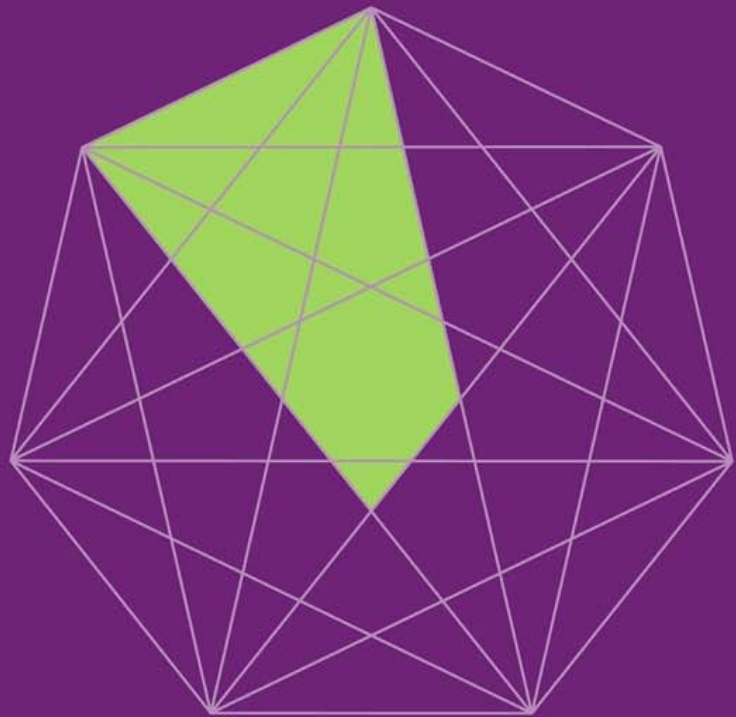


Longitudinal Registry

(Section C of Protocol)



1. Conway CR. et al. *Contemporary Clinical Trials* 95 (2020).



Path to Unlocking the Difficult-to-Treat Depression Opportunity

Jonathan Walker

U.S. General Manager & Global VP Difficult to Treat Depression

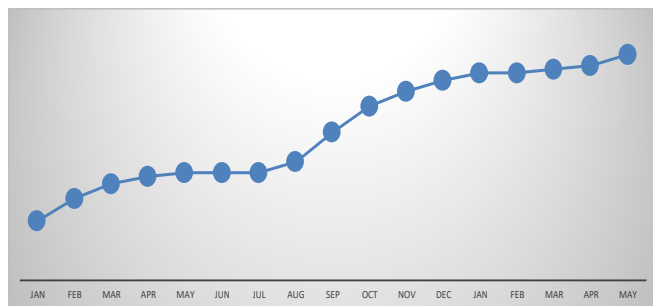
LivaNova
Depression

Study Status – key milestone achievement on track for Q4 2021

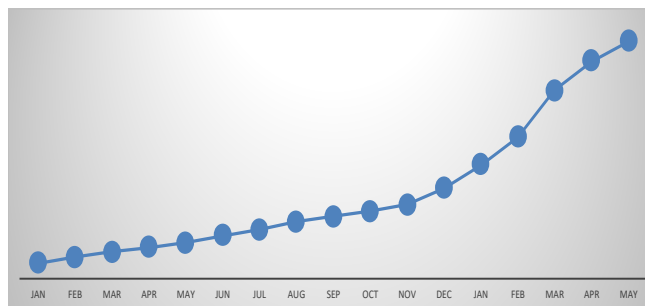
- Feb to Sept '20 study stopped implanting patients due to COVID-19
- Since Sept '20 significant progress has been made in site activations, patient consents and implants
- Next key milestone: Achieving 250 implanted unipolar and/or 150 bipolar patients

Study Status as of May 2021

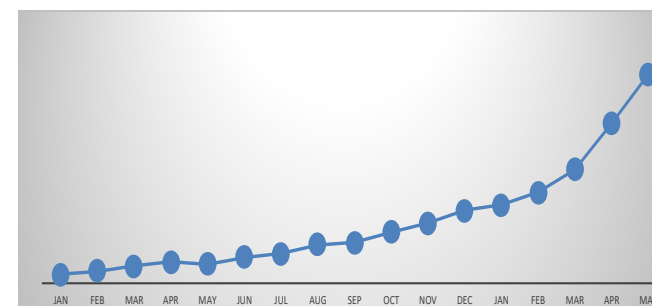
>75%
of sites activated



>50%
of patients consented

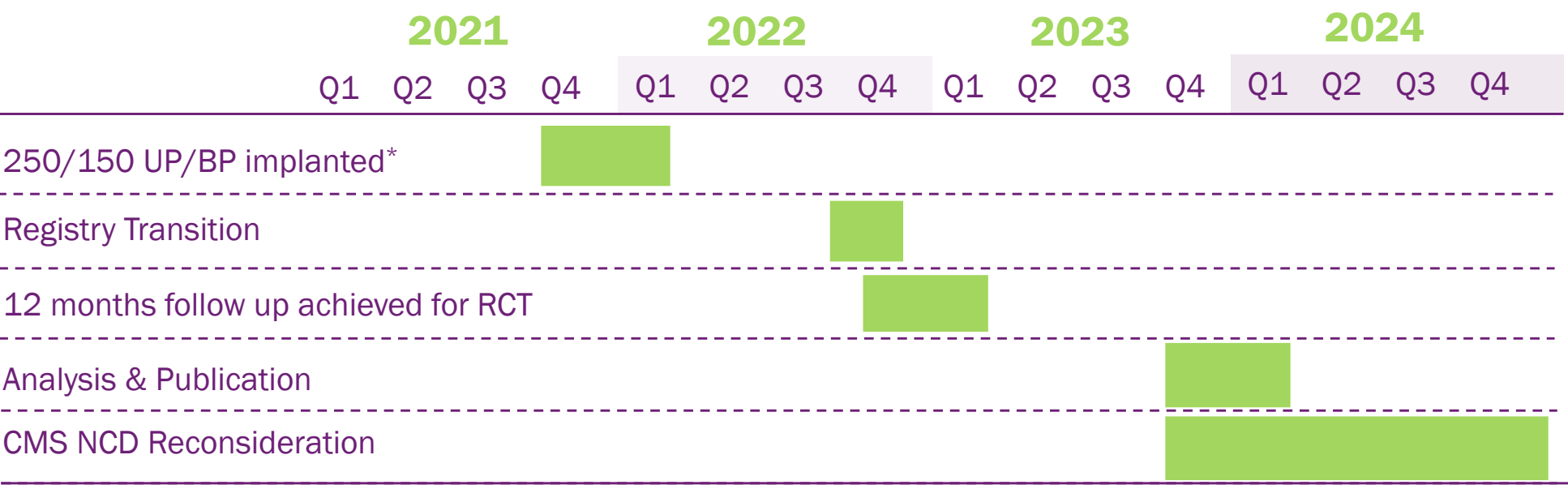


>33%
of patients implanted



RECOVER

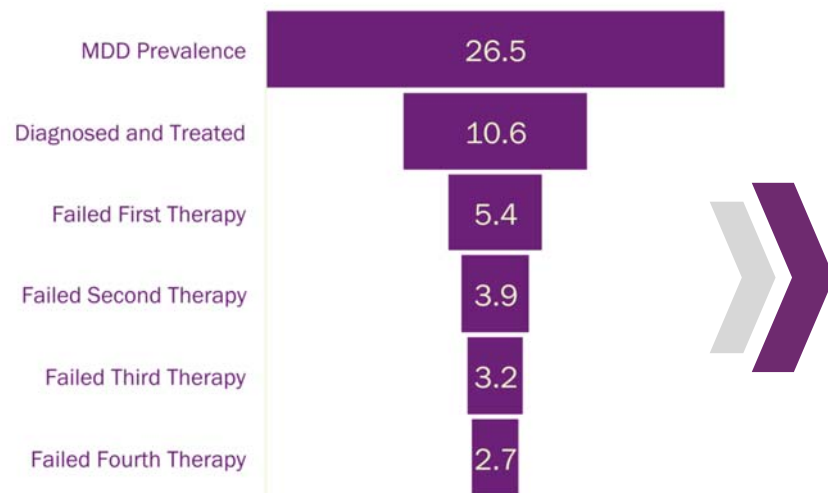
Current Planning Timelines for CMS NCD Reconsideration



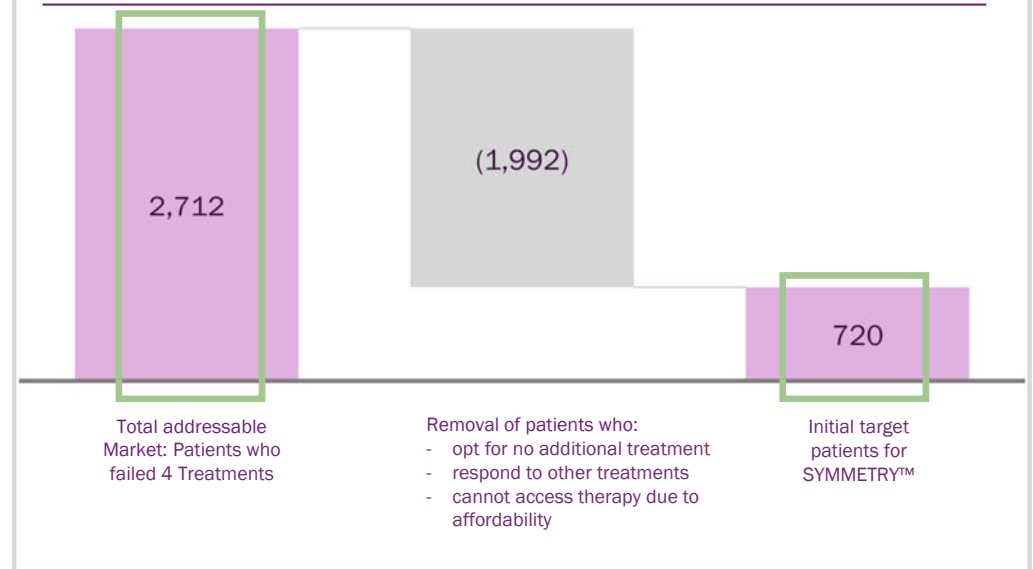
*The 1st interim analysis is triggered by the implant of either the 250th unipolar (UP) patient or the 150th bipolar (BP) patient.

Large number of patients in need of another treatment option

Prevalence in the US, # of patients, M

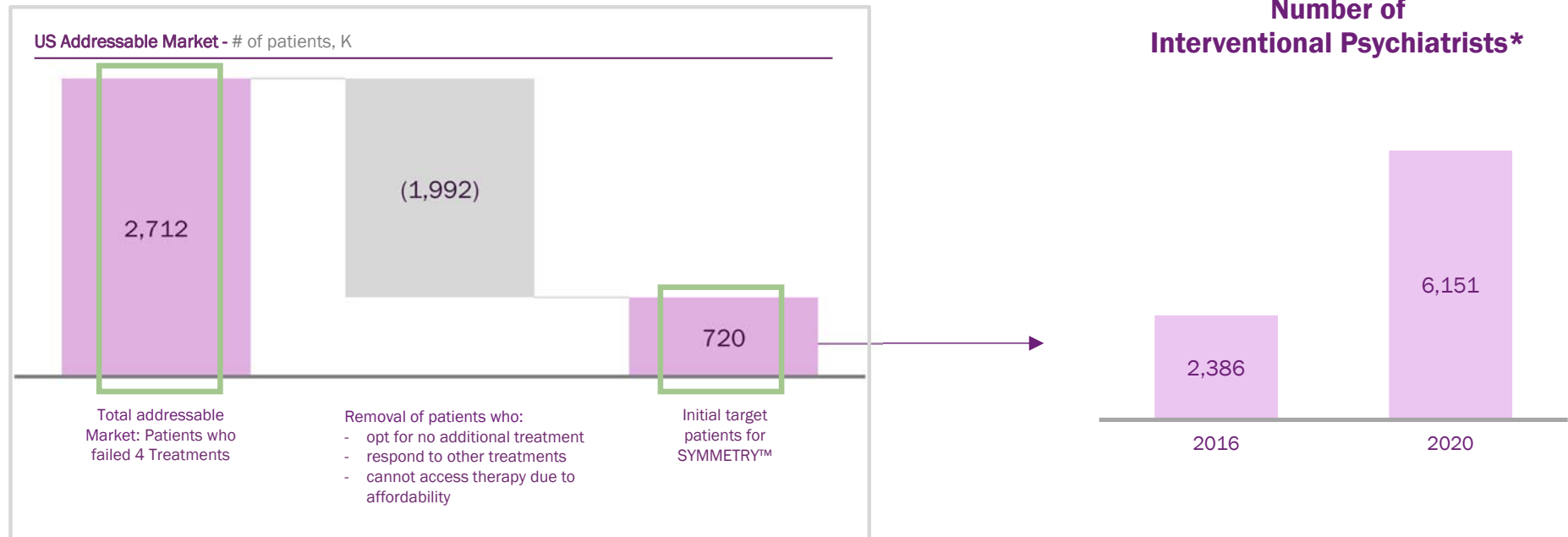


US Addressable Market - # of patients, K



- Sources and assumptions:
- MDD Prevalence: National survey of 36,309 US adults, the 12-month prevalence of major depressive disorder were 10.4%. Source 9: Hasin DS et al, Epidemiology of Adult DSM-5 Major Depressive Disorder and Its Specifiers in the United States. JAMA Psychiatry 2018;75(4):336-346. Ranges of data exists: 7.1% (National Institute of Mental Health), 8.1% (CDC), 5.9% (WHO). We used JAMA reference given the robust sample size and method (structured interviews).
 - Diagnosed and Treated: According to National Institute of Mental Health, 35% seek no treatment, 15% seek health professional only, 44% seek health professional and medication, and 6% seek medication only. We captured 50% of those who seek active medication treatment. Source 30: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>
 - Failed therapies: Applied failure rate of STAR*D: STAR*D response rates were 48.6%, 28.5%, 16.8%, 16.3% after first, second, third, and fourth treatment, respectively. Source 4: Rush et al. STAR*D report. Am J Psychiatry 2006; 163:1905-1917.
 - Patients who opt for no additional treatment after four failed therapy and who opt for additional treatment: Assumed 50% will seek no further treatment. Source 31: In the US qualitative patient market research (N=30, May 2020), we found 56% expressed significant interest and openness for VNS therapy post multiple therapy treatments failures which we extrapolated to additional therapy options.
 - ECT: Mental Health America estimates there are 100,000 people who receive this treatment each year in the US (Source 32: <https://www.mhanational.org/ect/>); ECT shows a response rate of 50% to 75% among non-responders to antidepressant medication. Considered ~35% as failure rate. (Source 23: Bschor T et.al., Chronic and Treatment Resistant Depression, 2014)
 - TMS: We estimate ~1M annual treatments in the US. Assuming 10 sessions to 30 sessions per patient (includes some drop out rate), estimate 33K-100K patients. However, given the non-invasive therapy and broader indication (2 failed treatment), we estimate that up to 30% of the patient pool could opt for initial treatment (400K patients). Response rates reported between 45% and 60%; estimated failure rate of ~50%. Source 33: Kelly MS et al. BA, J Neuropsychiatry Clin Neurosci. 2017 Spring; 29(2): 179-182.
 - Esketamine: Spravato has gained 7% market share in 2019 per DRG (market defined by ECT, TMS, and esketamine) and we estimate it will continue to grow given aggressive awareness and marketing. Estimate 6% (68K patients) of the patients can opt for Spravato in 2020+. Day 3 response rate post infusion is 54% (Source 35: Rong et al. Int J Environ Res Public Health. 2018 Apr; 15(4): 771). Assumed 50% failure rate over time.
 - Potential VNS Patients: 50% of the patients who opt for additional treatment who failed to respond ECT, TMS or esketamine + 56% of patients who shows interest or opt for VNS Therapy from 1.3M patient pool (based as an estimate from Patient Qualitative mkt research)
 - Market Access: Assumed 20% of the patients would not have market access to VNS (~20% of households have income less than \$25K a year - Source 43: Statista 2019).

Viable commercial model by hypertargeting interventional psychiatrists



*Interventional psychiatrists Market Definition: HCP's currently prescribing either ECT, TMS or esketamine IV/Nasal in DRG Medical Claims Data March 2020
DRG data only captures 60% of opportunity

Current and prior experience show significant interest in VNS

Uptake (2005-07):

~3,700 psychiatrists
prescribed VNS for
~16,000 patients*

Insight Work (2020):

>50% of DTD patients
express significant
interest (4 or 5 on 5-point
scale) around learning
more, being a potential
candidate for VNS (N=30)

Current In-Market Experience:

Almost 20,000 patients
have expressed an
interest in VNS**

* Data as of Jun 2007 ~3,300 DTD patients were implanted when coverage was removed

** Patients who filled out an online screen indicating interest for a VNS Therapy clinical trial as of May 2021

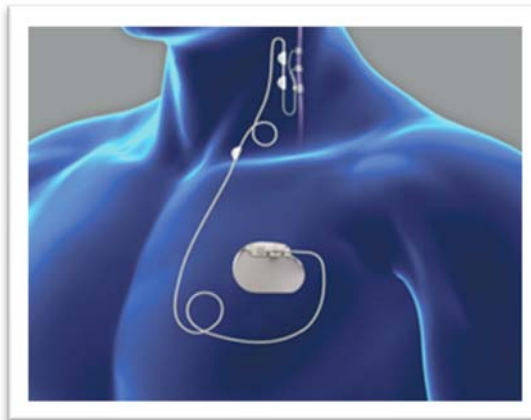


Quantitative research shows compelling reactions to VNS*

Most Compelling Features of VNS

Net Efficacy (79% unaided mentions)

- Response rate (32%)
- Efficacy unspecified (22%)
- Durability of response (15%)
- Remission rate (12%)
- Reduction in suicidality (11%)
- Time to response (7%)
- Effect in bipolar depression (4%)



Net Long-term Data (20%)

- Durability of response (15%)
- 5-year data (6%)

Net Administration (11%)

- Implant/non-pharmacologic (11%)
- Ensures patient compliance (3%)

Safety/Few side effects (9%)

Novel MOA (6%)

97% of psychiatrists said the VNS Therapy information provided is compelling

(n = 108)

* Percentages do not add up to 100% as they represent the number of unaided mentions among psychiatrists.



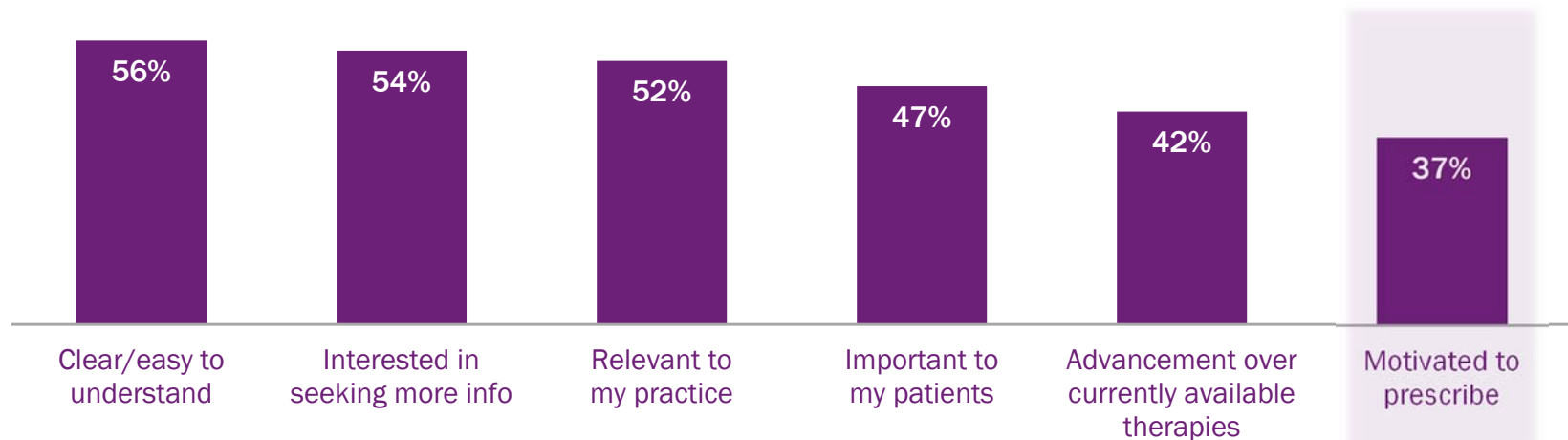
LivaNova

Psychiatrist Reactions to VNS Therapy

Over one third strongly motivated to prescribe VNS

Reactions to VNS Clinical Information

- Over half provide strong ratings for clear/easy to understand, interested in seeking more info and practice relevance



Overall, anticipated VNS use in 14%* of chronic recurrent DTD patients (18+)

(n = 108)

* Estimated VNS patient share was adjusted down by 25% from 18% to account for potential psychologist over-estimation.



LivaNova

Depression destroys life – VNS Therapy® restores life



- Kelsey grew up in Windhoek, Namibia. At 16 years old she started to develop severe symptoms of depression resulting from a concussion and started cutting herself. Her depression and anxiety continued to get worse. Multiple courses of antidepressants failed to help her
- The situation was so bad her mother rented a home in SC, U.S. for over a year for Kelsey to get treatment from Dr. Mark George
- 18 courses of TMS and ECT helped her depression initially, but her amnesia got so bad she had to “relearn” 3 years of math.
- In 2008, Dr. George recommended VNS Therapy and within 4 – 5 weeks after being implanted Kelsey said she was feeling much better. She finished high school, went to college at Saint Andrews and eventually went on to get her Masters degree in the UK.
- Kelsey now lives in London, got married two years ago and has her dream job as Assistant Curator at an art gallery. She also worked in NYC as the administrative assistant at MoMA.

Appendix

Links to Additional Information

- Symmetry Website
 - www.symmetryvns.com
- Depression Clinical Trial Design Publication
 - <https://www.sciencedirect.com/science/article/pii/S1551714420301440>