Vistagen

Corporate Presentation

Nasdaq: VTGN

Forward-looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve known and unknown risks that are difficult to predict and include all matters that are not historical facts. These forward-looking statements include information concerning our product candidates, development efforts, collaborations and/or potential strategic partnerships, intellectual property, financial condition, plans, development programs, prospects or future events and involve known or unknown risks that are difficult to predict. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "project," "outlook," "strategy," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "strive," "goal," "continue," "likely," "will," "would" and variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based upon estimates and assumptions that, while considered reasonable by us and our management, are inherently uncertain.

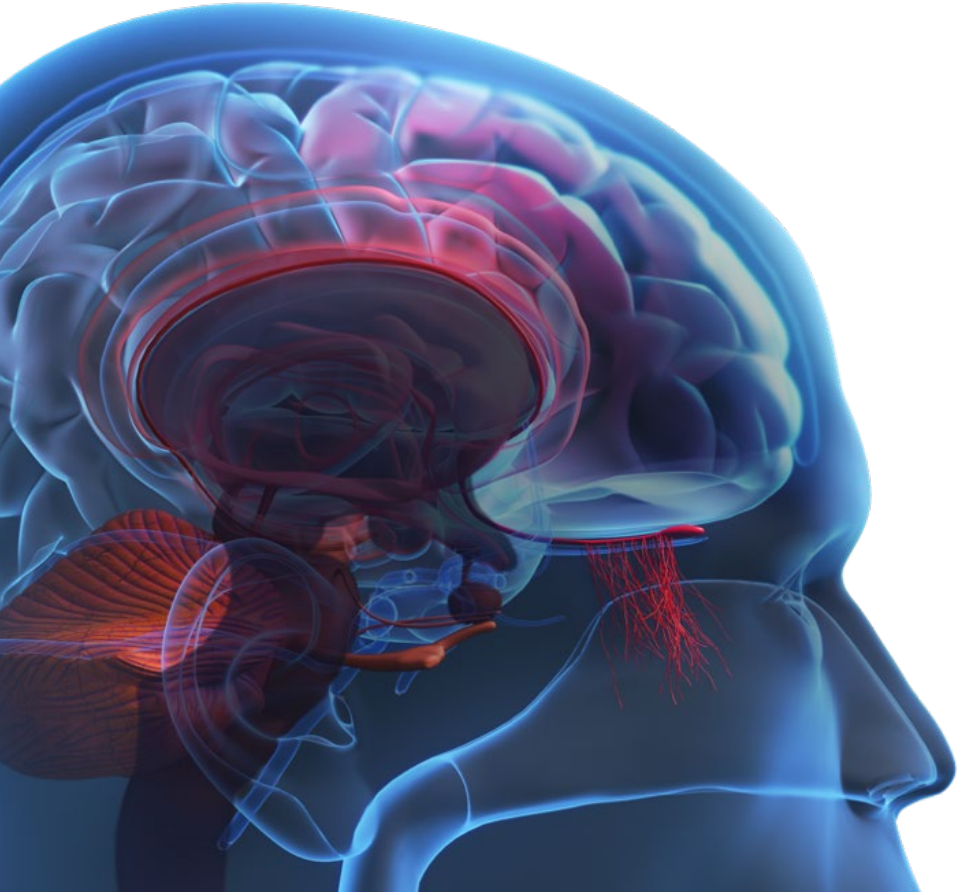
Our actual results or developments may differ materially from those projected or implied in these forward-looking statements, and there can be no assurance that any estimate and assumption contained within these forward-looking statements will materialize. As with all pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization and actual results or development may differ materially from those projected or implied in these forward-looking statements. Further, there can be no guarantee that any of our drug candidates will successfully complete ongoing or, if initiated, future clinical trials, receive regulatory approval or be commercially successful, or that we will successfully replicate the results of past studies of our product candidates, including fasedienol and itruvone. Other factors that may cause such a difference include, without limitation, risks and uncertainties related to our ability to secure funding that is adequate to support our development and commercialization plans and/or to secure successful strategic global and/or regional development and commercialization partnerships; other risks and uncertainties related to delays in launching, conducting and/or completing ongoing and planned clinical trials; the scope and enforceability of our patents, including patents related to our pherine drug candidates and AV-101; fluctuating costs of materials and other resources and services required to conduct our ongoing and/or planned clinical and non-clinical trials; market conditions; the impact of general economic, industry or political conditions in the United States or internationally; and other technical and unexpected hurdles in the development, manufacture and commercialization of our product candidates. These risks are more fully discussed in the section entitled "Risk Factors" in the Company's most recent Annual Report on Form 10-K for the fiscal year ended March 31, 2023, and in the Company's Quarterly Report on Form 10-Q for the period ended December 31, 2023, as well as discussions of potential risks, uncertainties, and other important factors in our other filings with the U.S. Securities and Exchange Commission (SEC). Our SEC filings are available on the SEC's website at www.sec.gov.

Given these uncertainties, you should not place undue reliance on these forward-looking statements, which apply only as of the date of this presentation and should not be relied upon as representing our views as of any subsequent date.

We explicitly disclaim any obligation to update any forward-looking statements, other than as may be required by law. If we do update one or more forward-looking statements no inference should be made that we will make additional updates with respect to those or other forward-looking statements. Be aware that our development and commercialization plans may change at any time, without public notice, based on the kinds of risk factors described above.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates and data.

Mission



Pioneering neuroscience to deliver groundbreaking therapies for individuals affected by psychiatric and neurological disorders

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Investment Highlights

- Deep neuroscience pipeline differentiated from current standards of care
- Targeting multiple large and diverse neuroscience markets
- Recent positive Phase 3 data for acute treatment of social anxiety disorder
- Potential NDA-enabling Phase 3 program funded
- Experienced neuroscience product development team and advisors

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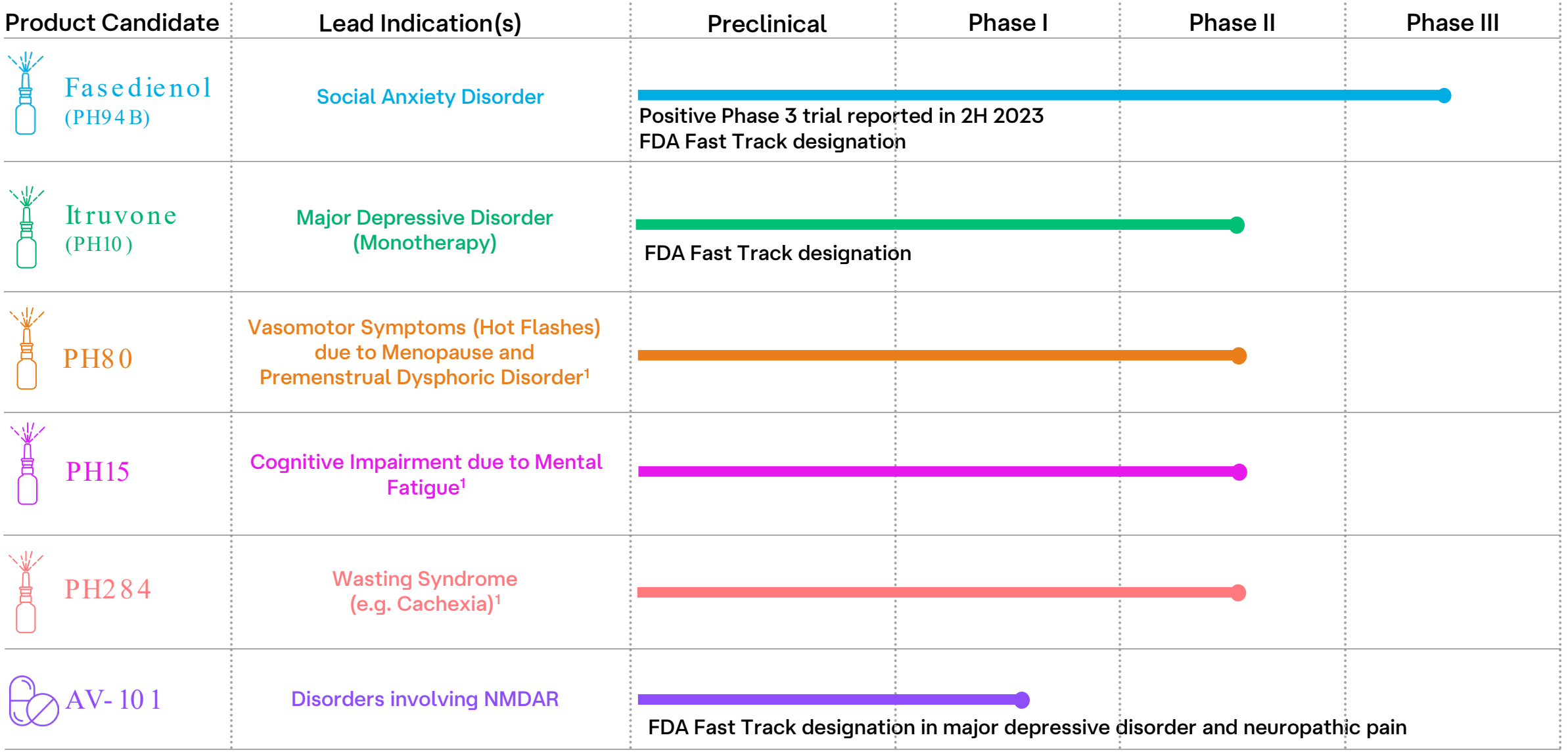
Clinical-stage Neuroscience Pipeline



1. Indicates U.S. IND-enabling work necessary to facilitate further Phase 2 clinical development in the U.S.

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Pherines

A novel class of neuroactive therapies

Pherines

Novel neurocircuitry-focused candidates for psychiatric and neurological disorders

- Differentiated MOAs
- Delivered intranasally
- Rapidly active
- Odorless and tasteless

- Activate neural circuitry connected to regions of the brain that impact multiple and diverse disorders
- Do not need to be taken systemically to have an effect on neurons in the brain
- Do not bind to abuse liability receptors
- Favorable safety profiles observed in all clinical trials completed to date

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Fasedienol Nasal Spray for the Acute Treatment of Social Anxiety Disorder

Setting a new standard of care for anxiety disorders

Social Anxiety Disorder Is a Serious Mental Health Condition

SAD is not medicalized shyness. It is a chronic disorder characterized by …

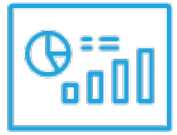
Debilitating emotional and physical symptoms

Emotional Symptoms
- Overwhelming fear
- Surges of anxiety
- Extreme self-consciousness
- Isolation leading to depression

Physical Symptoms
- Blushing / Sweating
- Trembling
- Nausea
- Fast heartbeat / Chest discomfort
- Shortness of breath / Dizziness

In everyday social or performance situations

Meeting new people



Presenting at work or school

Public speaking

Interviewing for a job

Eating/drinking in front of others

Making a phone call

Source: ADAA Social Anxiety Brochure 2021

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SAD Affects ~10% of the U.S. Population

It has been over 2 decades since the current SAD therapies were approved by the FDA

Treatable Patients

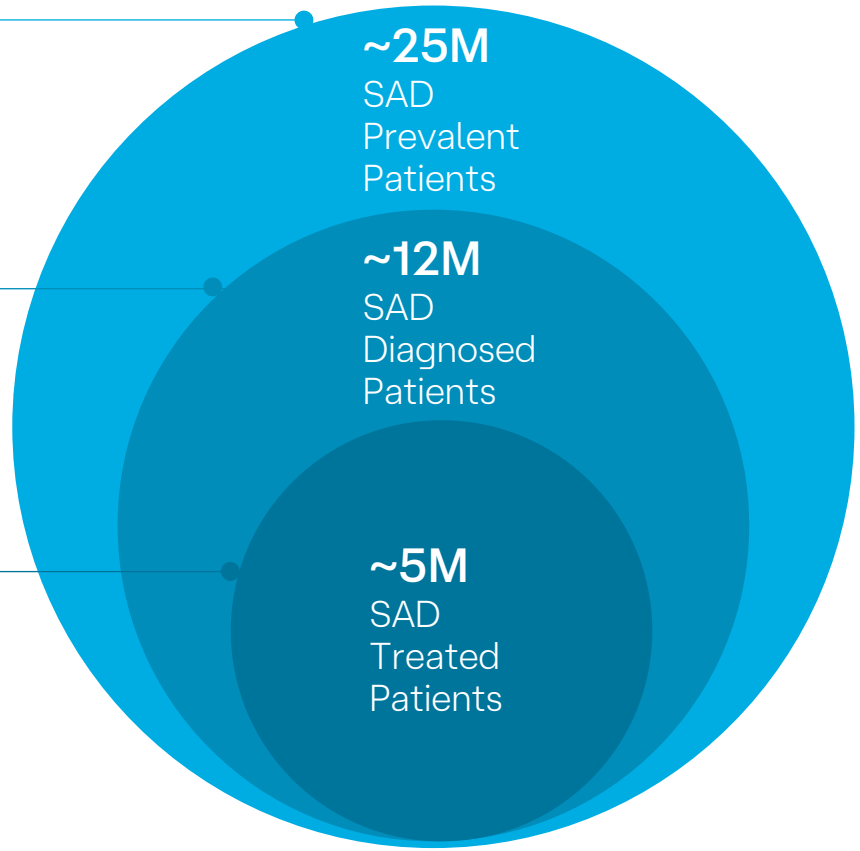
Patients suffering but unaware they may have SAD or not yet motivated to seek professional help

Underserved Patients

Patients unsatisfied with or unwilling to use current treatment options due to efficacy, side effects, or addiction potential

Existing Patients

Patients cycling through treatments, often unsatisfied with their current treatment options but without alternatives



Sources: Kantar Health. Nov 2021. National Health and Wellness Survey (NHWS), 2021. [U.S.]. Malvern, PA.

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Current FDA-Approved Pharmacotherapy Falls Short of Physicians' Preferred Product Profile for Treatment of SAD

There is no FDA-approved acute treatment for SAD

Desired Product Profile of Treatments for Social Anxiety Disorder							
Drug	Fast-acting	Non-systemic	No Long-term Side Effects	Non-sedating*	No Cognitive/ Motor Impairment	No Withdrawal Syndrome	No Abuse Potential
FDA-approved (sertraline, paroxetine, venlafaxine)	⊖	⊖	⊖	✓	✓	⊖	✓
Off-label (benzodiazepines)	✓	⊖	⊖	⊖	⊖	⊖	⊖
Physicians' Preferred SAD Therapy	✓	✓	✓	✓	✓	✓	✓

* Non-sedative hypnotic agents

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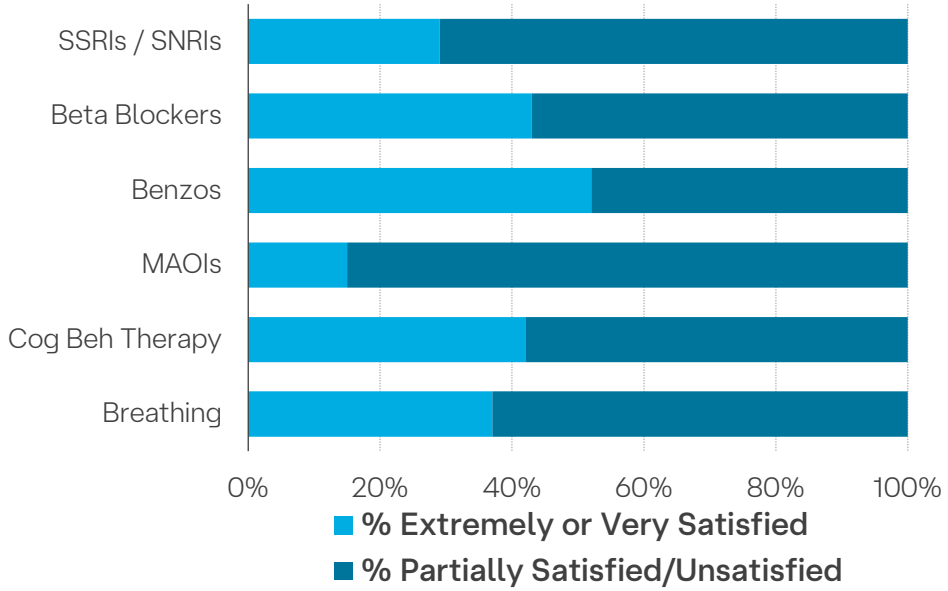
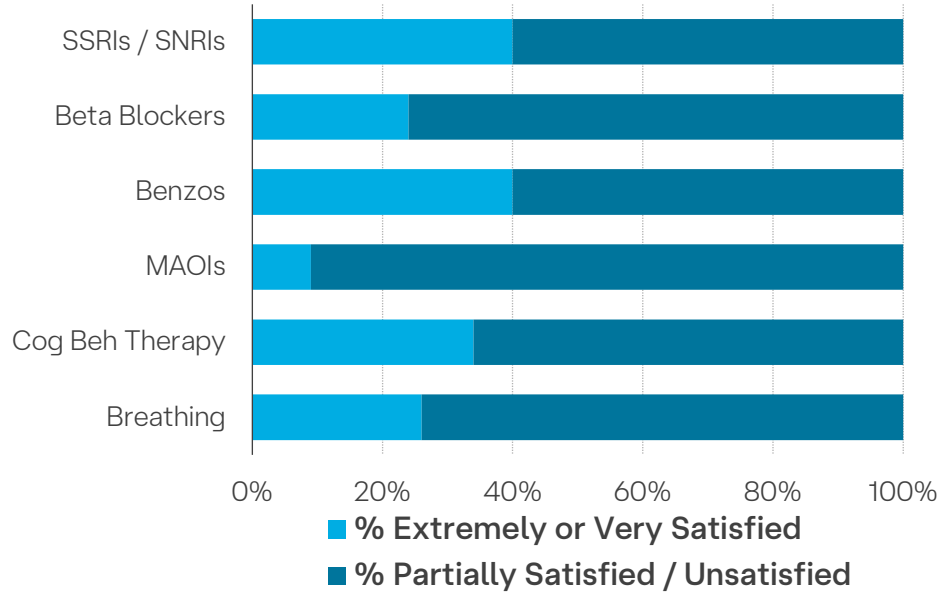
Physician Satisfaction with Therapies Currently Prescribed for Acute Episodes of SAD Is Modest

Psychiatrists (n=125)



Primary Care Physicians (n=126)



Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022

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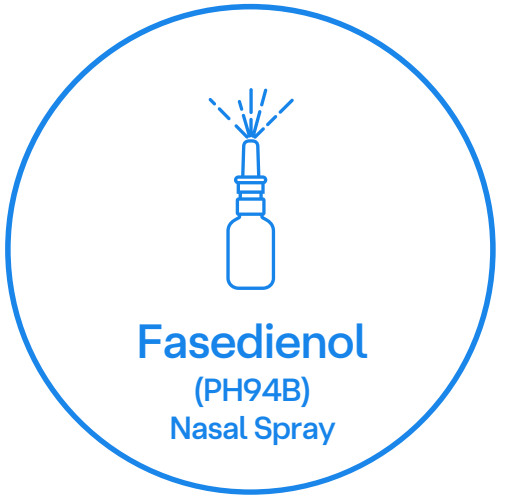
Fasedienol Brings New Optimism for the Acute Treatment of SAD

- De-risked potential NDA*-enabling pathway with positive Phase 3 results in 2H 2023
- Novel mechanism of action (MOA) differentiated from all FDA-approved products
- Designed for patient-tailored administration, with potential use analogous to an as-needed rescue inhaler for asthma
- No observed systemic absorption or direct activity on neurons in the brain
- Does not potentiate GABA or bind to abuse liability receptors
- Favorable tolerability profile, no evidence of abuse liability potential
- Potential to build confidence and reduce fear, anxiety, and avoidance of stressors
- FDA Fast Track designation granted



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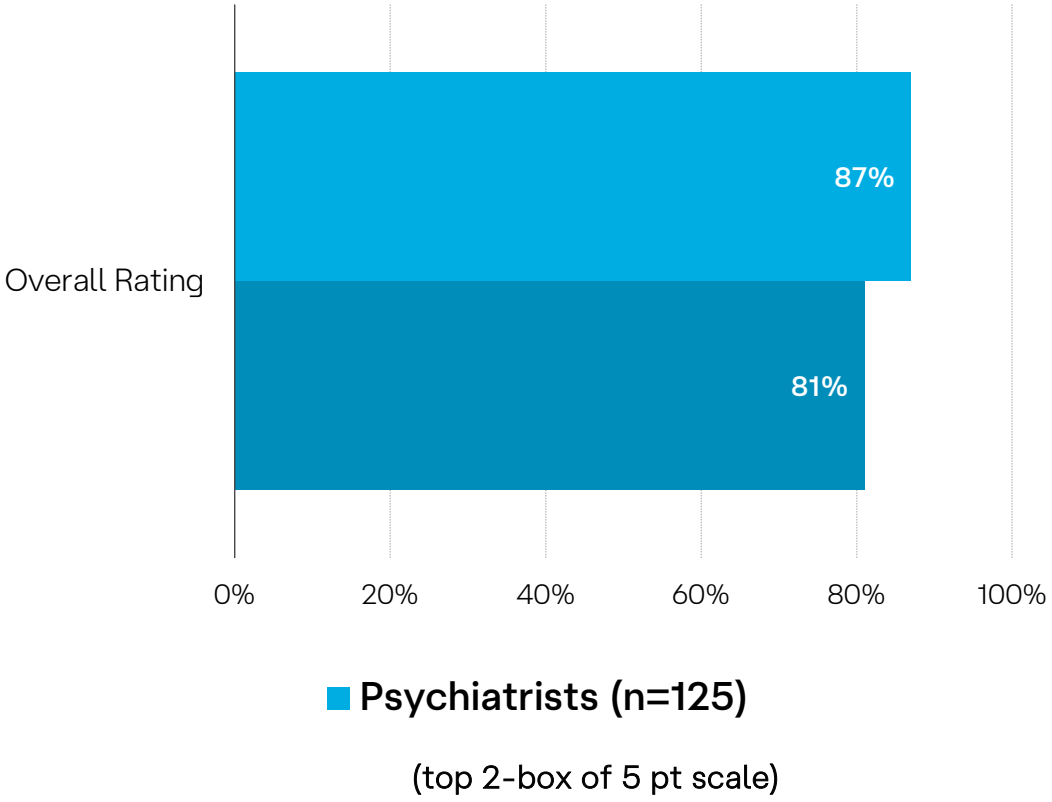
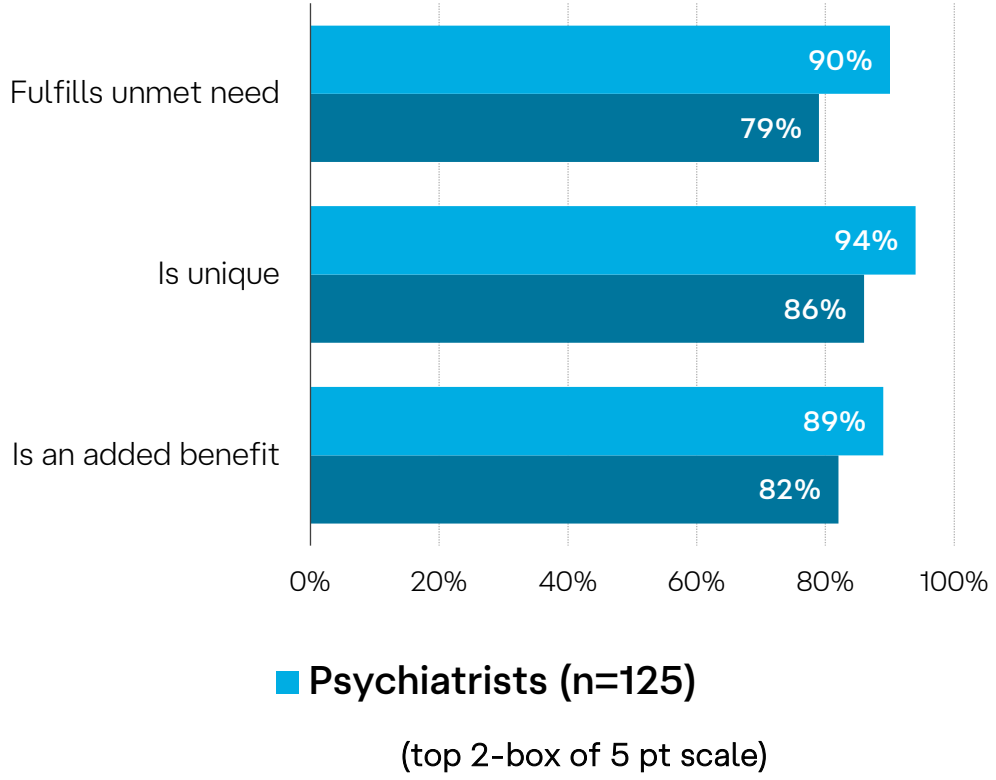
*NDA = New Drug Application

Blinded Fasedienol Target Product Profile Rated Highly by Psychiatrists and Primary Care Physicians





Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022 (n=251)

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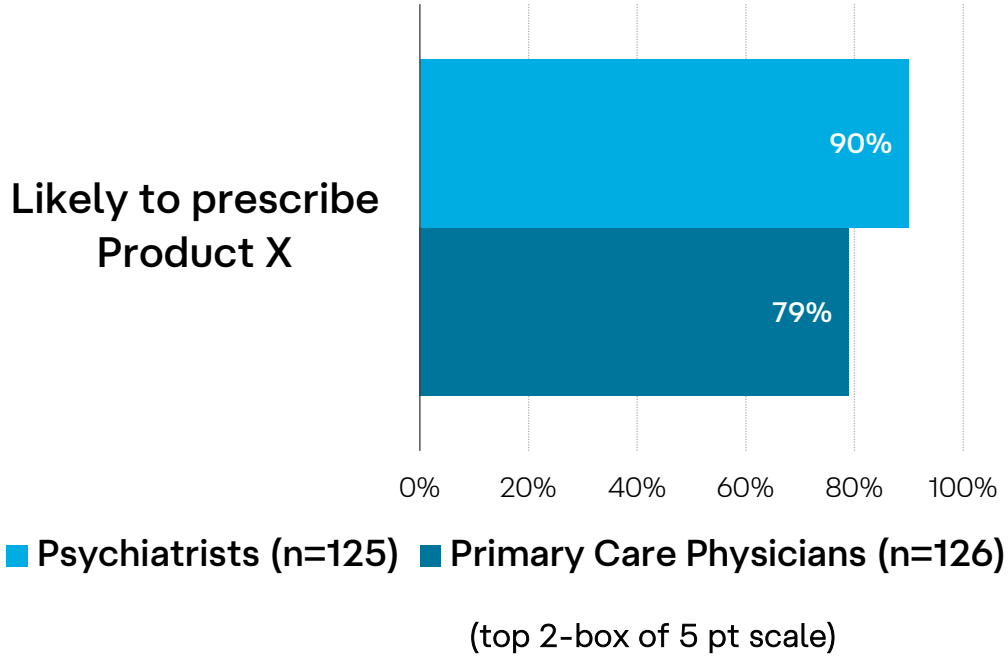
Psychiatrists and Primary Care Physicians Indicate High Intent to Prescribe a Product with Fasedienol's Profile and Note it Would Be Appropriate for the Majority of their SAD Patients



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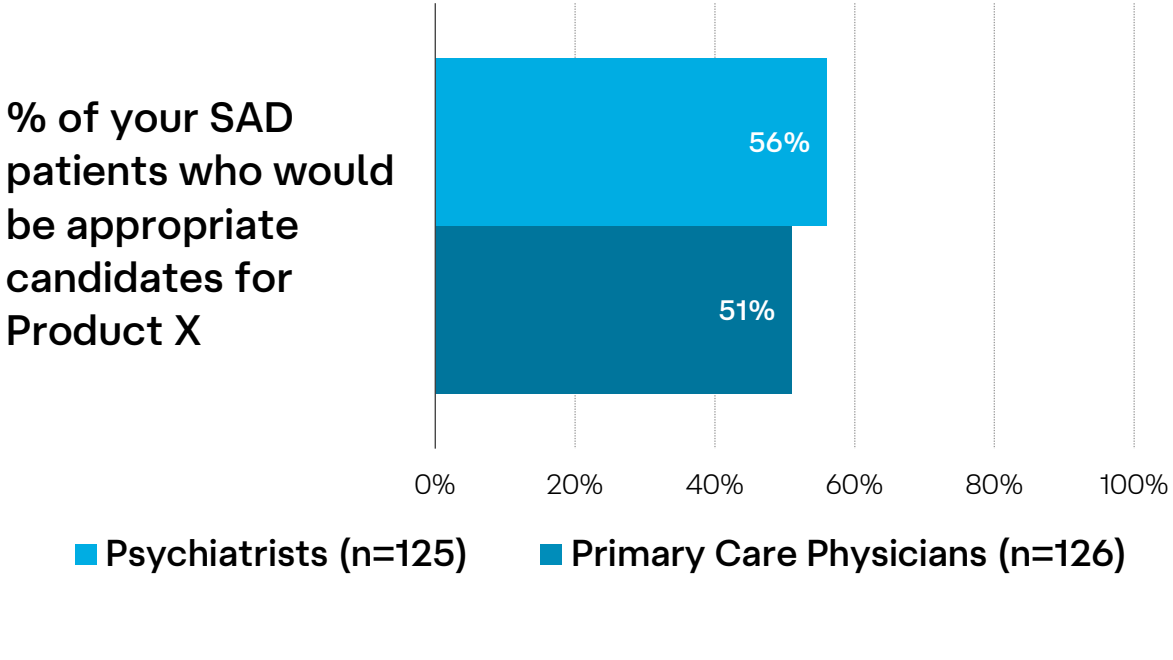

Sources: Vistagen Proprietary Market Research, Online Survey, Jan 2022 (n=251)

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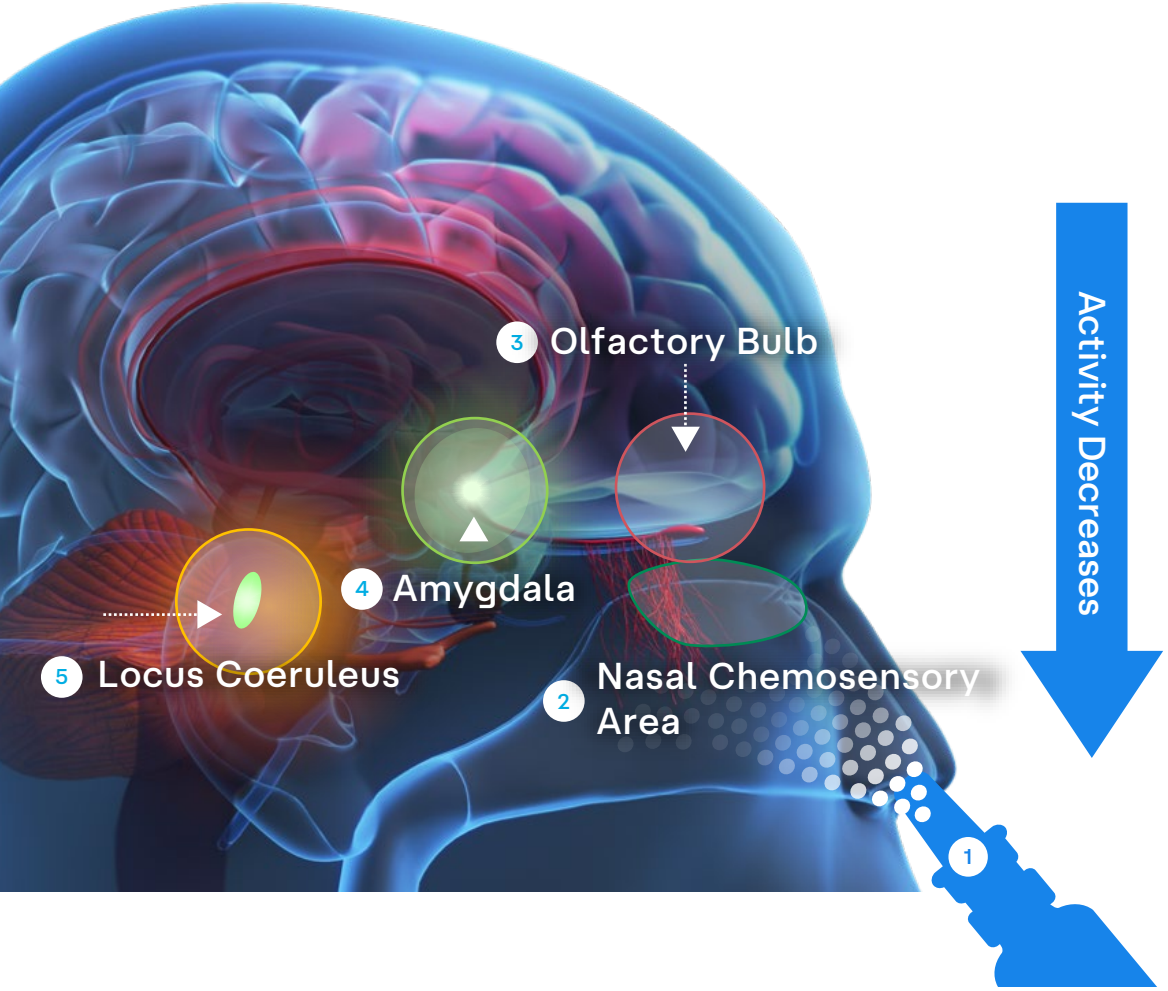
Fasedienol's Novel Proposed Mechanism of Action

Differentiated from all current therapies for anxiety disorders



1. A microgram-level dose of fasedienol is administered intranasally
2. Fasedienol engages specific peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs trigger olfactory bulb neurons (OBs)
4. OBNs stimulate inhibitory GABAergic "Fear Off" neurons in the limbic amygdala, the main fear and anxiety center of the brain
5. Stimulation of the limbic amygdala DECREASES activity of the sympathetic nervous system, which facilitates fear extinction activity of the limbic-hypothalamic system, as well as in other parts of the brain

Sources: Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

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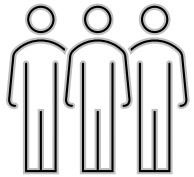
PALISADE-2 Phase 3 Trial for Acute Treatment of SAD

PALISADE-2

Public speaking challenge



Study Design

A U.S. randomized, multi-center, double-blind, placebo-controlled, single-dose administration Phase 3 trial to evaluate the efficacy, safety, and tolerability of fasedienol for the acute treatment of anxiety in adult subjects with social anxiety disorder induced by a public speaking challenge in a clinical setting

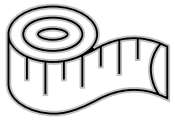
Screening Criteria

Inclusion Criteria

+ SAD diagnosis; LSAS > 70
+ HAMD < 18 at screening
+ Normal olfactory function, Quick Olfactory Test if suspected necessary
+ No recent history of COVID-19

Exclusion Criteria

— Significant psychiatric illness, use of psychotropic medication
— Suicidal behavior
— Alcohol or substance use disorder
— Significant nasal pathology



Outcome Measures

Primary Endpoint

- Change in mean Subjective Units of Distress (SUDS) scores from baseline compared to placebo

Secondary Endpoint

- Responder Rates based on Clinical Global Impression – Improvement (CGI-I)

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PALISADE-2 Phase 3 Trial Top-Line Efficacy Results

Positive results across primary, secondary, and exploratory endpoints

Met Primary Endpoint	**LS Mean SUDS change from baseline vs. placebo** (SUDS change from Visit 2 to Visit 3)	p=0.015
Met Secondary Endpoint	**CGI-I proportion of responders vs. placebo** (much or very much less anxious from Visit 2 to Visit 3)	p=0.033
Met Exploratory Endpoints	**PGI-C proportion of responders vs. placebo** (much or very much less anxious from Visit 2 to Visit 3)	p=0.003
	SUDS proportion of responders vs. placebo (≥20-point improvement from Visit 2 to Visit 3)	p=0.020

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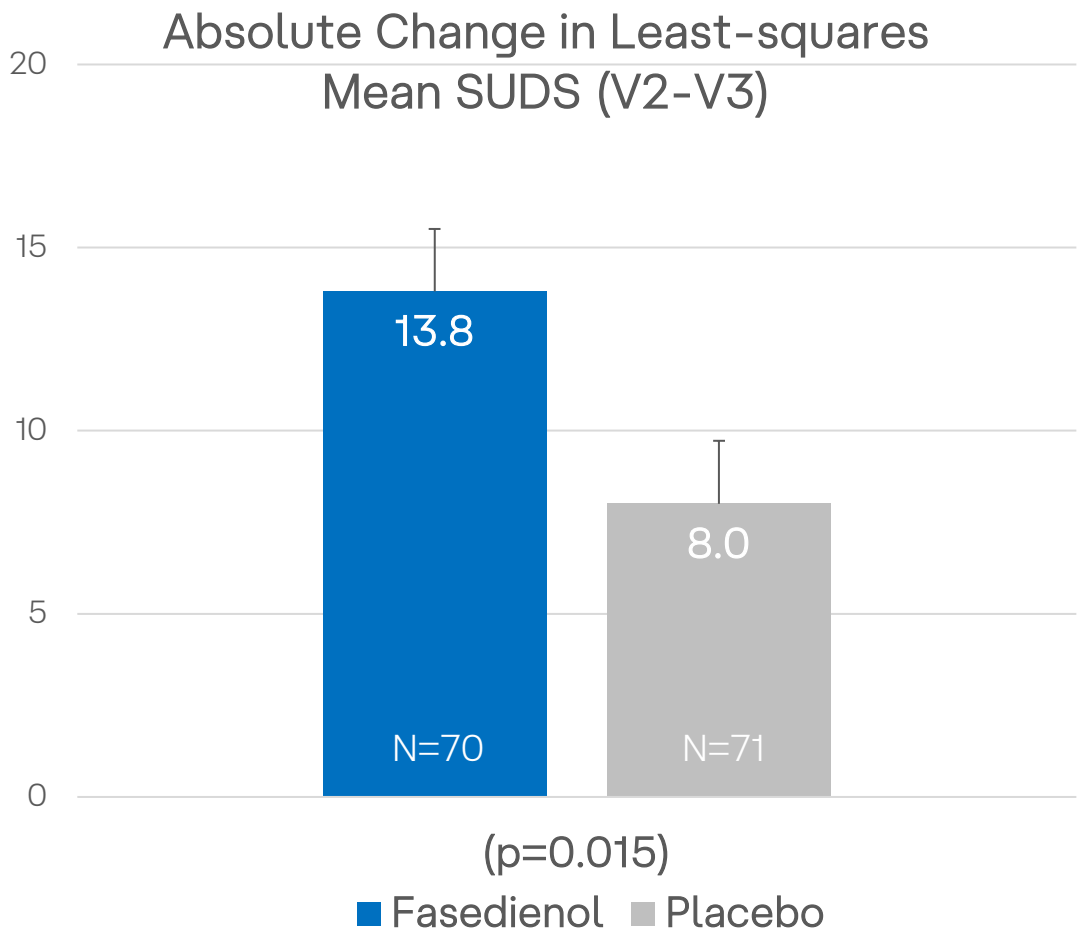
PALISADE-2 Primary Efficacy Endpoint: Change in Least-squares Mean SUDS Scores from V2 to V3 vs. Placebo

PALISADE-2

Met primary efficacy endpoint with a change from Baseline of 5.8 points better than placebo



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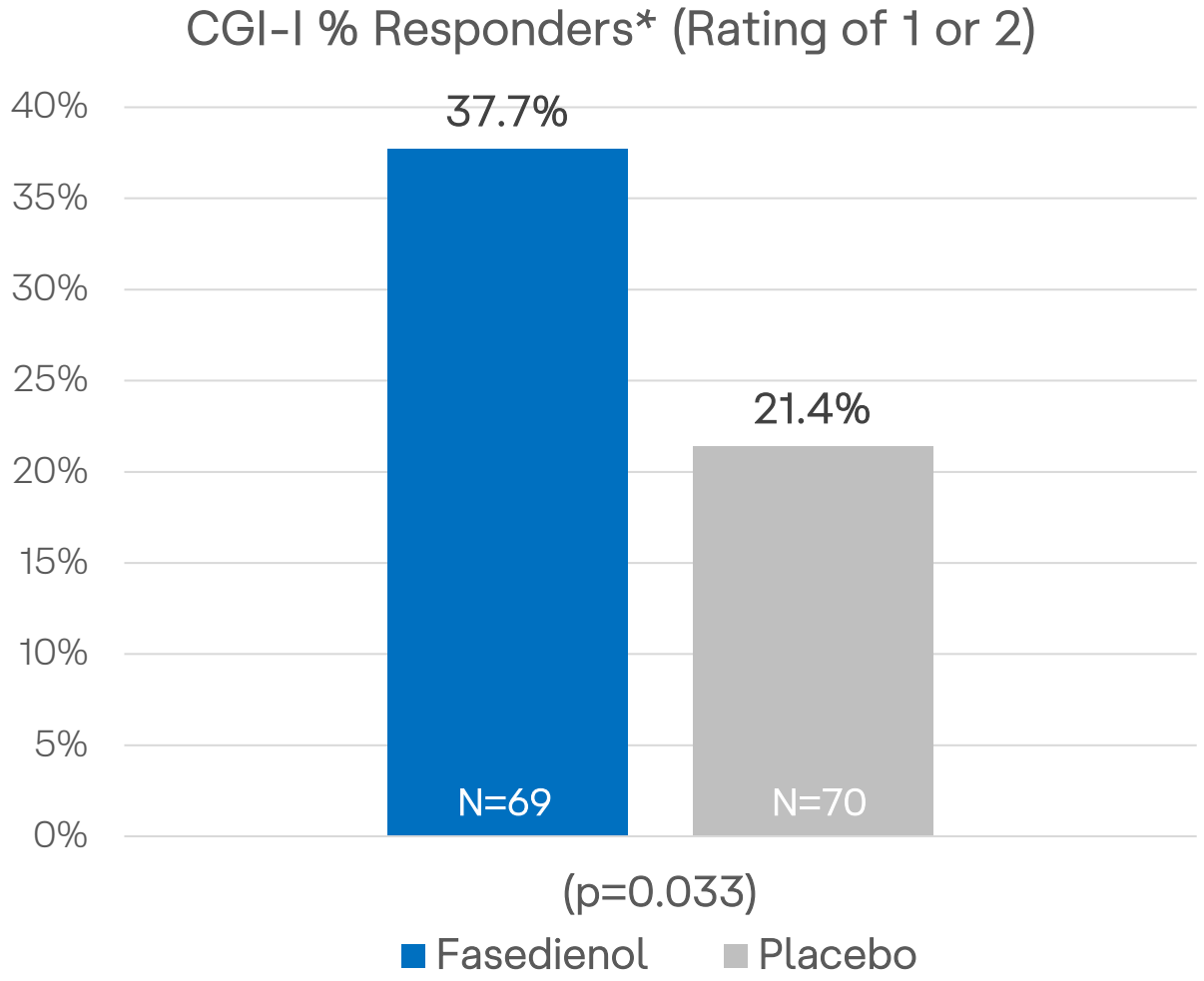
PALISADE-2 Secondary Efficacy Endpoint: CGI-I Responders vs. Placebo at V3

Met secondary efficacy endpoint; fasedienol responders 1.8 times greater than placebo



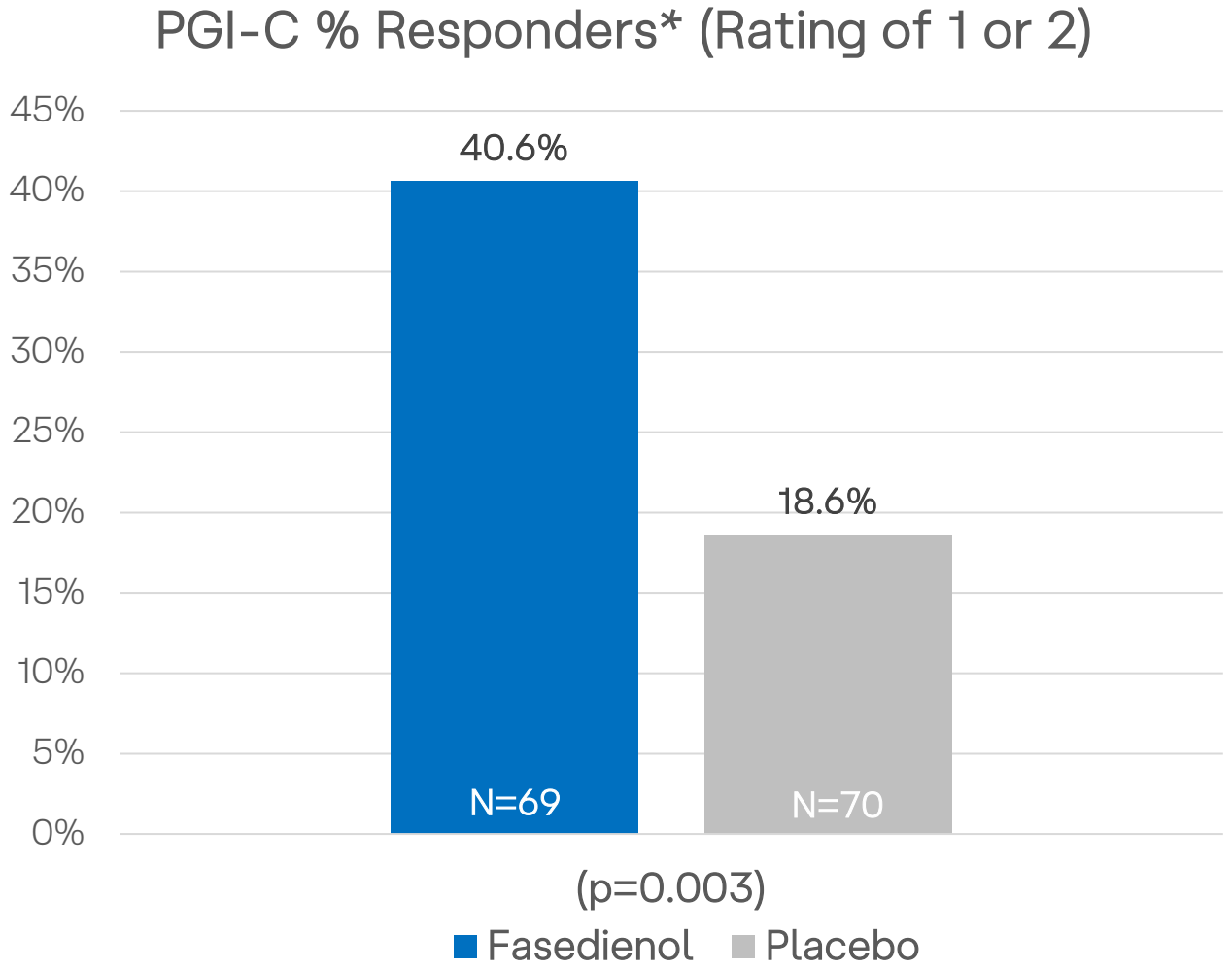
CGI-I Score

1 = Very Much Less Anxious
2 = Much Less Anxious
3 = A Little Less Anxious
4 = No Change
5 = A Little More Anxious
6 = Much More Anxious
7 = Very Much More Anxious

* In accordance with FDA-aligned, pre-specified statistical analysis plan, missing CGI-I values for one subject on placebo and one subject on fasedienol were not imputed for the ITT CGI-I responder analysis. The missing values resulted from site error and are considered missing at random.

PALISADE-2 Exploratory Endpoint: PGI-C Responders vs. Placebo at V3

Met exploratory endpoint; fasedienol responders 2.2 times greater than placebo



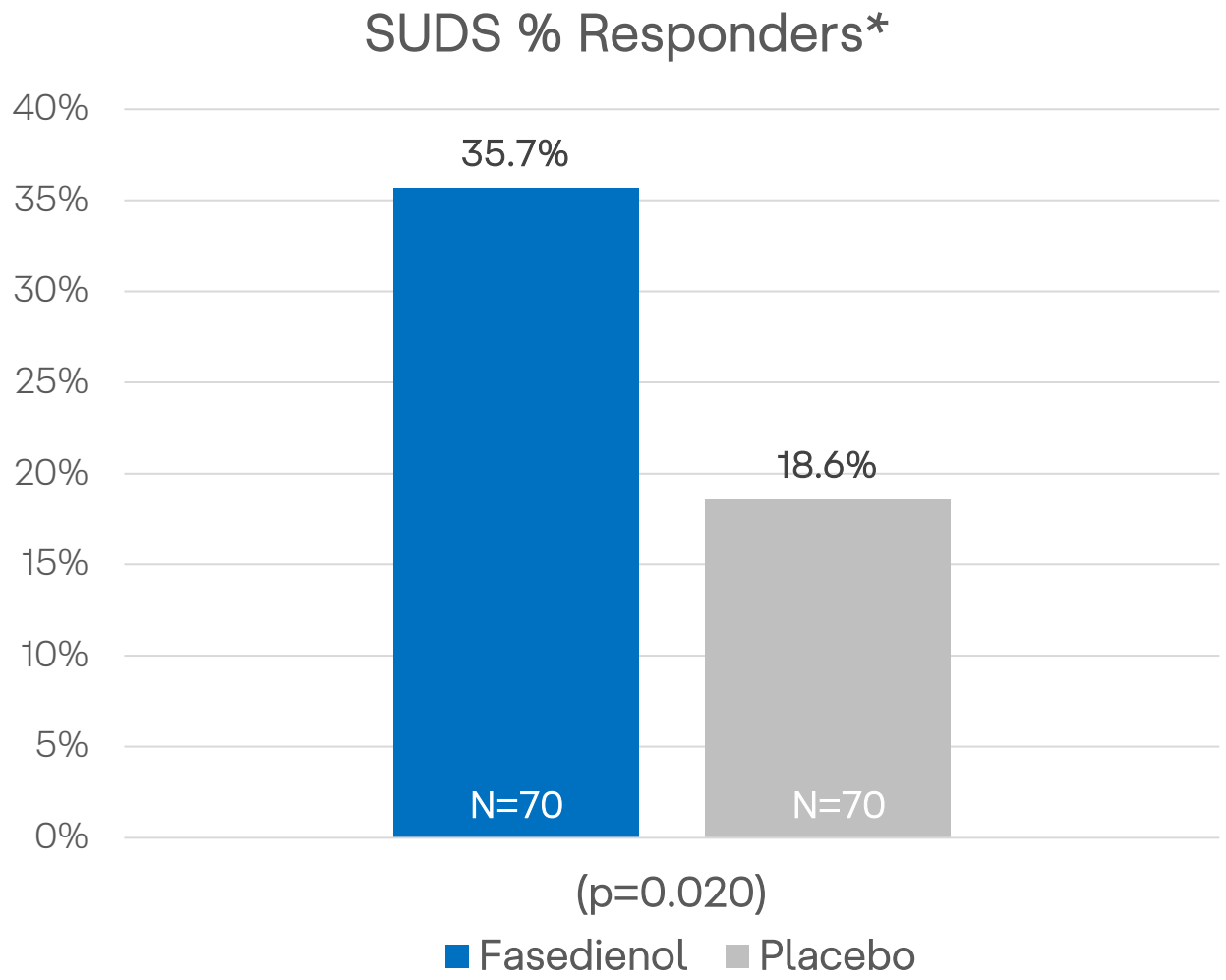
PGI-C Score

1 = Very Much Less Anxious
2 = Much Less Anxious
3 = A Little Less Anxious
4 = No Change
5 = A Little More Anxious
6 = Much More Anxious
7 = Very Much More Anxious

* In accordance with FDA aligned, pre-specified statistical analysis plan, missing PGI-C values for one subject on placebo and one subject on fasedienol were not imputed for the ITT PGI-C responder analysis. The missing values resulted from site error and are considered missing at random.

PALISADE-2 Exploratory Endpoint: SUDS Responders vs. Placebo at V3

Met exploratory endpoint; fasedienol responders 1.9 times greater than placebo



SUDS Responders
≥ 20-point improvement from Visit 2 baseline to Visit 3

* In accordance with FDA-aligned, pre-specified statistical analysis plan, missing V3 SUDS values for one subject on placebo were not imputed for the ITT SUDS responder analysis. The missing values resulted from site error and are considered missing at random.

PALISADE-2 Tolerability Profile

PALISADE-2

The tolerability profile of fasedienol was favorable and consistent with results from all fasedienol trials completed to date

- No severe or serious adverse events were reported
- No discontinuations due to adverse events following the single dose of fasedienol
- Adverse events were infrequent and mild or moderate in severity
- There were no treatment-emergent adverse events (TEAEs) reported above a 2% occurrence, except pyrexia in the placebo group (2.49%)

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PALISADE Open Label Safety Study

PALISADE-LTSS

Over 30,000 doses self-administered in daily life by 481 SAD patients

Design

Long-term self-administration of 3.2 µg of fasedienol as-needed, up to 4x/day prior to anxiety-provoking social and performance stressors in daily life, with a mean study duration of 4 months, and a maximum study duration of over 10 months

Results

- Long-term self-administration of 3.2 µg of fasedienol as-needed, up to 4x/day, was well-tolerated in adult SAD patients (n=481)
- Of the 481 SAD participants in the study who received at least one dose of fasedienol, at least one treatment-emergent adverse event (TEAE) was reported by 56.8% of subjects, with 54.9% of the 481 participants reporting mild or moderate TEAEs and only 1.9% of participants reporting severe TEAEs
- **Headache was the most common TEAE** (17.0%; 8.7% drug-related); COVID-19 infection was reported by 11.4% (0% drug-related) of participants
- **No other TEAE occurred in more than 5.0% of participants**

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Fasedienol Potential U.S. NDA-enabling Phase 3 Clinical Plan*

To complement PALISADE-2, Vistagen is preparing to initiate two additional Phase 3 clinical studies of fasedienol for the acute treatment of SAD

PALISADE-3 and PALISADE-4 Phase 3 Trials with Open-label Extension (OLE)

Design: Phase 3 Acute Treatment Public Speaking Challenge similar to PALISADE-2

Potential OLE: Up to 12 months

Timing: Preparing to begin PALISADE-3 in 1H 2024 and PALISADE-4 in 2H 2024

Target enrollment: Approximately 230 in each Phase 3 study

Vistagen believes either PALISADE-3 or PALISADE-4, if successful, together with PALISADE-2, may establish substantial evidence of the effectiveness of fasedienol in support of a potential U.S. NDA submission to the FDA for the acute treatment of anxiety in adults with SAD

*Initiation of each of these Phase 3 studies is subject to FDA feedback

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PALISADE-3 and PALISADE-4 Phase 3 SAD Trials with OLE*

PALISADE

Study Design

Randomized, multi-center, double-blind, placebo-controlled, single-dose administration Phase 3 trial to evaluate the efficacy, safety, and tolerability of fasedienol for the acute treatment of anxiety induced by a public speaking challenge in adult subjects with social anxiety disorder in a clinical setting

Criteria

Inclusion Criteria

+ Female and male subjects; age 18-65
+ SAD diagnosis; LSAS ≥ 70; HAMD<18
+ Normal olfactory function determined by Quick Olfactory Test
+ Medical and psychiatric health

Exclusion Criteria

— Nasal swab within the past four weeks
— COVID-19 diagnosis + any residual symptoms within past 4 weeks
— Drug use (incl. cannabis), heavy use of alcohol, smoking, vaping
— Other primary psychiatric disorders; receiving CNS active medications

Outcome Measures

Primary Endpoint

- Change in mean SUDS scores from V2 to V3 compared to placebo

Secondary Endpoints

Responder rates at V3 vs placebo:

- Patient Global Impression of Change
- Clinical Global Impression – Improvement

*OLE = Open Label Extension. Vistagen is preparing to initiate these Phase 3 studies in 2024, subject to FDA feedback

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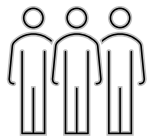
Fasedienol Phase 2 Repeat Dose Study with OLE*



Study Design

Randomized, multi-center, double-blind, placebo-controlled, repeat-dose administration Phase 2B trial to evaluate the efficacy, safety, and tolerability of a repeat dose of fasedienol for the acute treatment of anxiety induced by a public speaking challenge in adult subjects with social anxiety disorder in a clinical setting

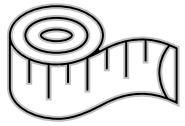
Criteria

Inclusion Criteria

+ Female and male subjects; age 18-65
+ SAD diagnosis; LSAS ≥ 70; SUDS ≥ 75 at V2
+ Normal olfactory function determined by Quick Olfactory Test
+ Medical and psychiatric health

Exclusion Criteria

— Nasal swab within the past four weeks
— COVID-19 diagnosis + any residual symptoms within past 4 weeks
— Drug use (incl. cannabis), heavy use of alcohol, smoking, vaping
— Other primary psychiatric disorders; receiving CNS active medications



Outcome Measures

Primary Endpoint

- Change in mean SUDS scores from V2 to V3 for single dose and repeat dose compared to placebo

Secondary Endpoint

Responder rates at V3 vs placebo:

- Patient Global Impression of Change
- Clinical Global Impression – Improvement

*OLE = Open Label Extension. Vistagen is preparing to initiate this Phase 2 study in 2H 2024, subject to FDA feedback

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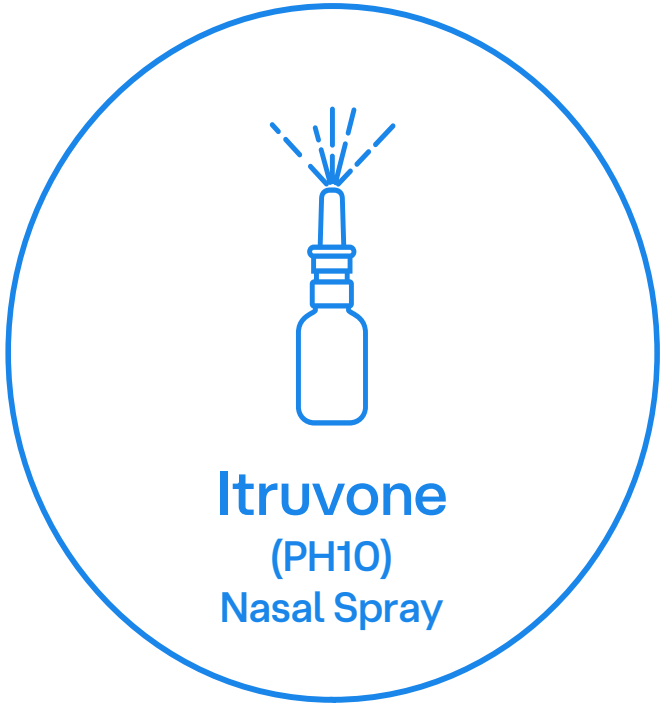
Itruvone Nasal Spray for Major Depressive Disorder

Setting a new standard of care for depression disorders

Itruvone is a Novel Potential Monotherapy for Major Depressive Disorder (MDD)

- Innovative odorless, tasteless synthetic neuroactive nasal spray
- Designed for rapid-onset antidepressant effects
- Differentiated MOA from all approved antidepressants
- Observed to be non-systemic, non-sedating, non-addictive; does not bind to GABA receptors to potentiate GABA
- Positive exploratory Phase 2A trial (n=30)
- Well-tolerated in all clinical studies to date
- FDA Fast Track designation granted



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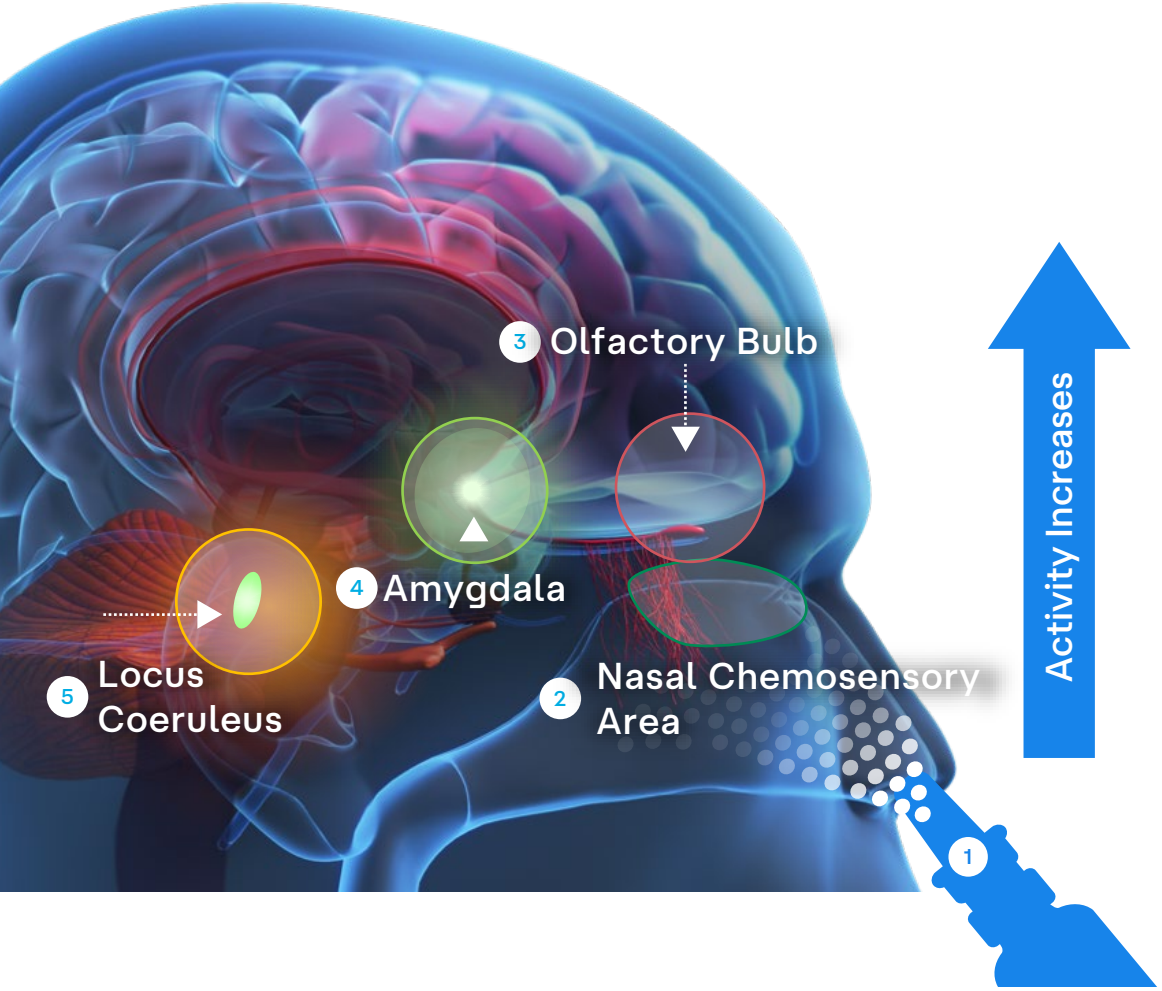
Ituruvone's Novel Proposed Mechanism of Action

Differentiated from all current therapies for depression disorders



1. Microgram-level intranasal dose of ituruvone is administered intranasally
2. Ituruvone engages specific peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs trigger subgroups of interneurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then stimulate GABAergic and CRH neurons in the limbic amygdala
5. The stimulation of the limbic amygdala INCREASES the activity of the sympathetic autonomic nervous system and the release of catecholamines from the midbrain

Sources: Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

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Itruvone Phase 2A Study in MDD

Design: Phase 2A randomized, double-blind, placebo-controlled, parallel design POC clinical study (n=30)

Dosing: 3.2 µg or 6.4 µg of itruvone or placebo i.n., 2 times per day for 8 weeks

Primary Endpoint: Change in HAMD-17 scores from baseline compared to placebo

Results:

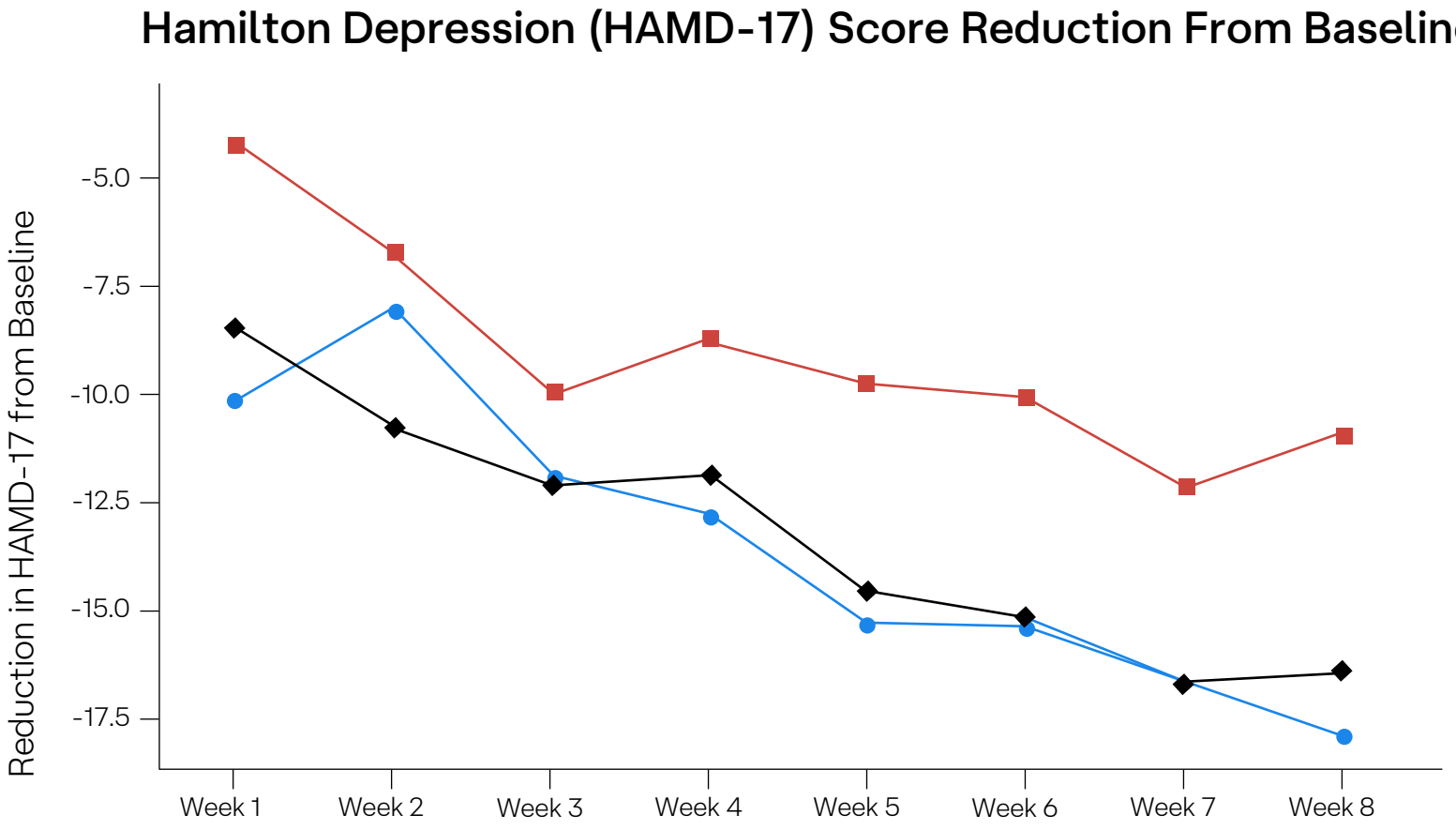
- **6.4 µg dose significantly reduced depressive symptoms as early as one week based on HAMD-17 scores compared to placebo (p=0.022)**
- 3.2 µg dose showed a trend (p=0.101)
- Strong effect sizes for both 3.2 µg and 6.4 µg vs. placebo at 1 week and at 8 weeks

Safety & Tolerability: Well-tolerated, no serious adverse events observed, no dissociative side effects, no reports of weight gain or sexual dysfunction

Rapid-onset antidepressant effects with itruvone observed in MDD study participants with minimal side effects

Sources: Monti, L., Nicolini, H., Liebowitz, M., & Hanover, R. (2019). "A Placebo Controlled Trial of PH10: Test of a New Rapidly Acting Intranasally Administered Antidepressant." *Br J Phar Med Res* 4(6): 2157-2168.

Ituruvone Phase 2A Study in MDD



6.4 µg dose produced rapid-onset and sustained antidepressant effects in MDD study participants with minimal side effects

Ituruvone Dose	HAMD-17 Score	p (itruvone vs placebo)	Cohen's D (Effect Size)
◆ 3.2 µg (Low Dose)	-16.3	0.101	0.74
● 6.4 µg (High Dose)	-17.8	0.022	0.95
■ Placebo	-10.9	--	--

Sources: Monti, L., Nicolini, H., Liebowitz, M., & Hanover, R. (2019). "A Placebo Controlled Trial of PH10: Test of a New Rapidly Acting Intranasally Administered Antidepressant." *Br J Phar Med Res* 4(6): 2157-2168.

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Ituruvone Phase 2B Clinical Plan*

Planning for potential Phase 2B development of itruvone as an innovative, non-systemic monotherapy for MDD is underway

Potential Design: Double-blind, randomized, placebo-controlled, parallel study in approximately 200 total male and female subjects (18 to 65 years old) with a confirmed diagnosis of MDD, who are not currently taking any antidepressants

Outpatient self-administration of 6.4 µg (3.2 µg twice daily) itruvone nasal spray over a 4-week period

Potential Primary Efficacy Endpoint: Change from Baseline to Day 28 in the HAMD-17 Rating Scale

*Potential Initiation of this Phase 2B study is subject to FDA feedback

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PH80 Nasal Spray for Vasomotor Symptoms (Hot Flashes) due to Menopause

Setting a new standard of care

PH80 Nasal Spray

Potential treatment for vasomotor symptoms (hot flashes) due to menopause and premenstrual dysphoric disorder

- Innovative, rapid-onset product candidate
- Novel and differentiated MOA from all approved products
- Taken as-needed for treatment of multiple menopausal hot flashes, potential use analogous to a rescue inhaler for asthma
- Potential to provide relief in the moment, as well as reduce the number and severity of hot flashes over time
- No systemic absorption or direct action on CNS neurons
- Potential safety and tolerability profile advantages over currently approved therapies
- Positive exploratory Phase 2A studies completed in menopausal hot flashes (n=36) and premenstrual dysphoric disorder (n=52)

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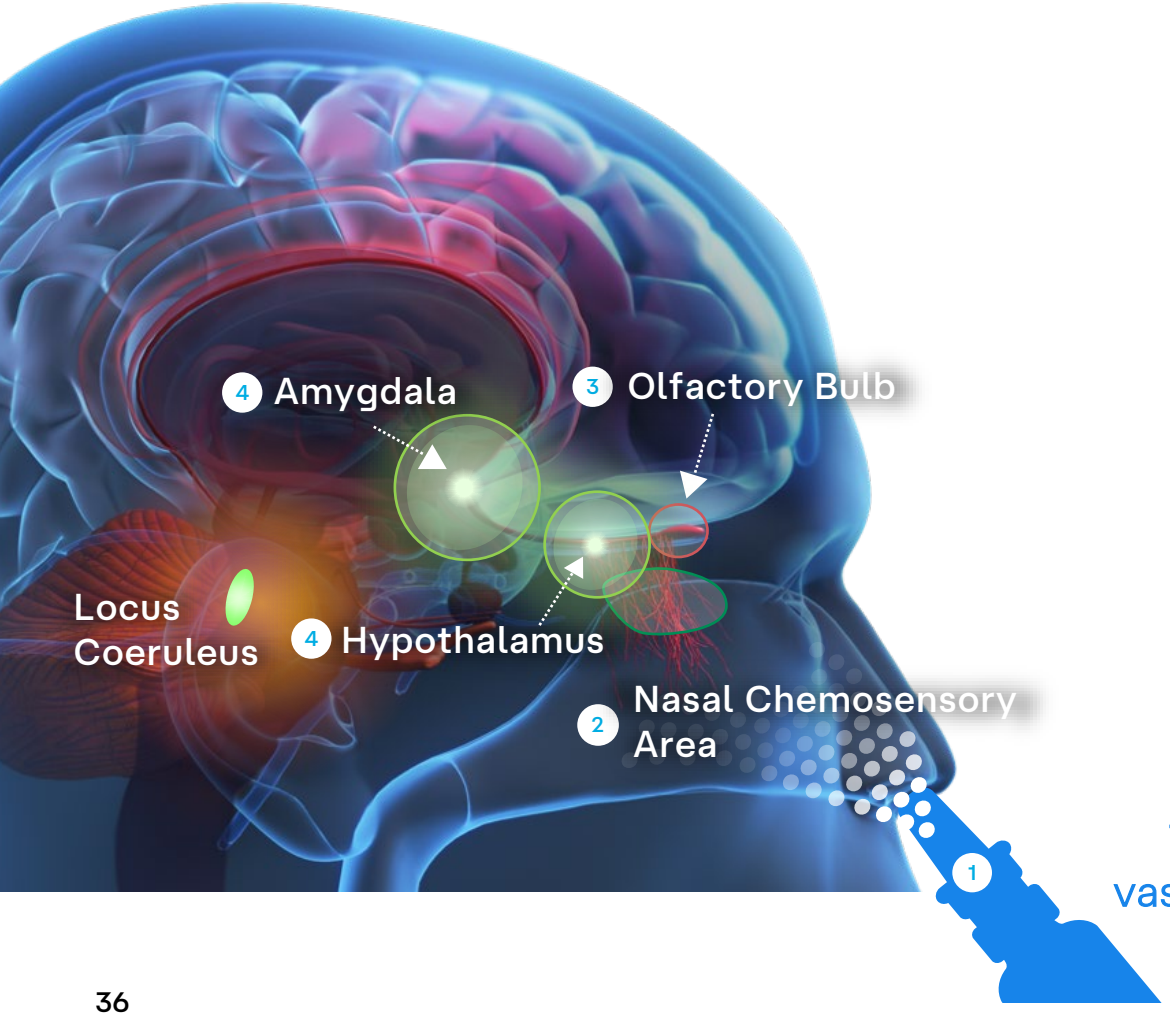
PH80's Novel Proposed Mechanism of Action

Differentiated from all currently approved VMS therapies



1. Microgram-level intranasal dose of PH80 is administered intranasally
2. PH80 engages specific peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs then trigger subgroups of neurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then stimulate neurons in the limbic amygdala and the hypothalamus

Activity Decreases

The stimulation of neurons in the limbic amygdala and the hypothalamus decreases the activity of the autonomic nervous system and decreases activation of the trigeminal-vascular neural circuits

Downstream effects potentially include:

- Decreased irritability;
- Decreased muscle tension;
- Reduced core body temperature; and
- Reduced feeling of internal heat

These changes potentially affect the neural circuits involved in vasomotor symptoms (hot flashes) due to menopause, premenstrual dysphoric disorder (PMDD), and migraine

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Source: Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

PH80 Phase 2A Study in Hot Flashes

Objective: Proof-of-principle evaluation of PH80 efficacy and tolerability for the management of VMS (hot flashes) due to menopause

Study Details: Randomized, double-blind, placebo-controlled, Phase 2A study. Participants self-administered PH80 (3.2 µg/dose) or placebo for 4 weeks up to 4 times daily with a dose at night if needed (up to 16 µg/day). Participants were followed up weekly during the treatment period

Participants: Menopausal women aged 45-60 (n=36) with ≥ 8 hot flashes of moderate to severe intensity per day on average for 1 week (≈ 56/week)

Outcome Measures: Daily ratings of the Number, Severity, Disruption in function (Bother), and Sweating associated with daily hot flashes, PGI-C, CGI-I, Safety, and Tolerability

Results: PH80 showed statistically and clinically significant improvement vs. placebo in the number and severity of hot flashes while also significantly reducing participant-reported disruption in function and sweating associated with hot flashes

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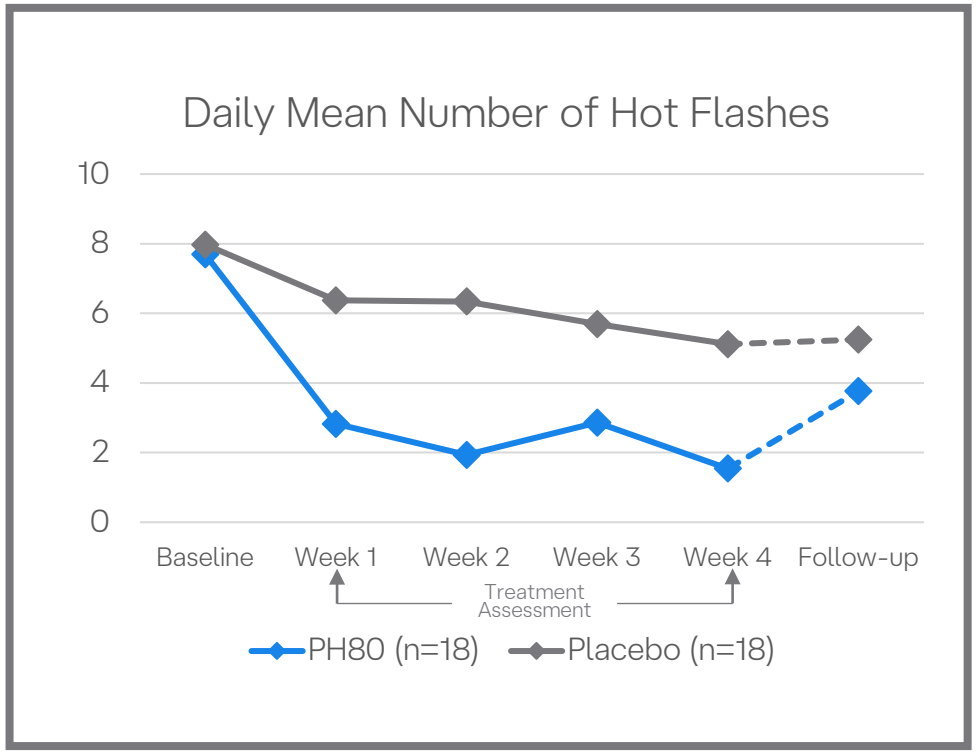
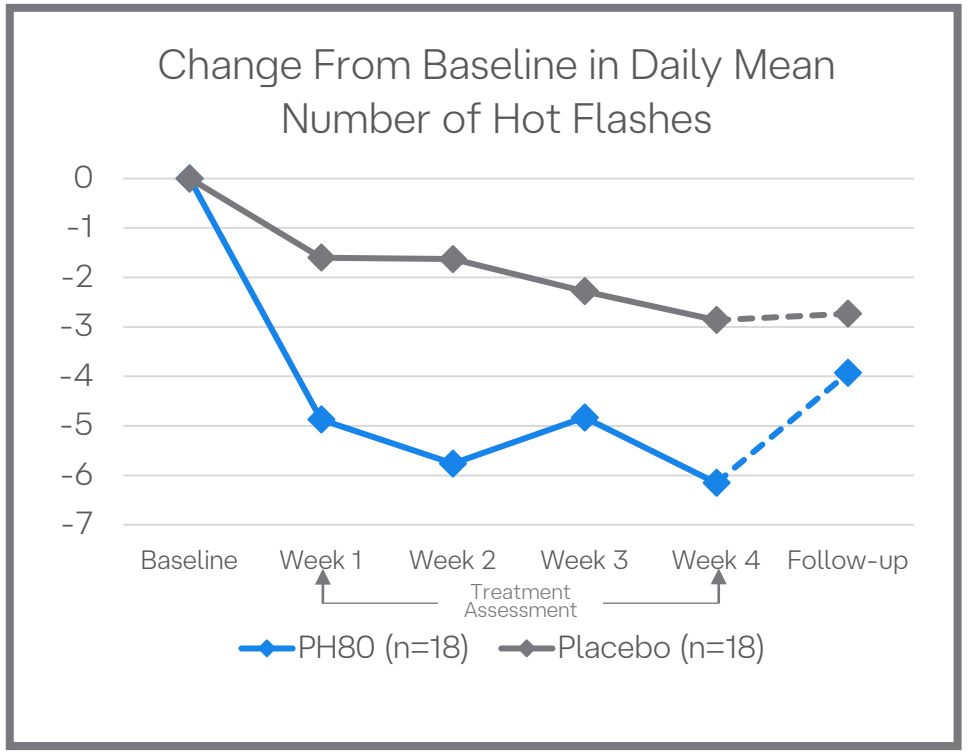
PH80 Phase 2A Study in Hot Flashes: Met Primary Efficacy Endpoint

Statistically and clinically significant improvement vs. placebo in the number of hot flashes at 1 week and maintained through 4 weeks of treatment (p<0.001)





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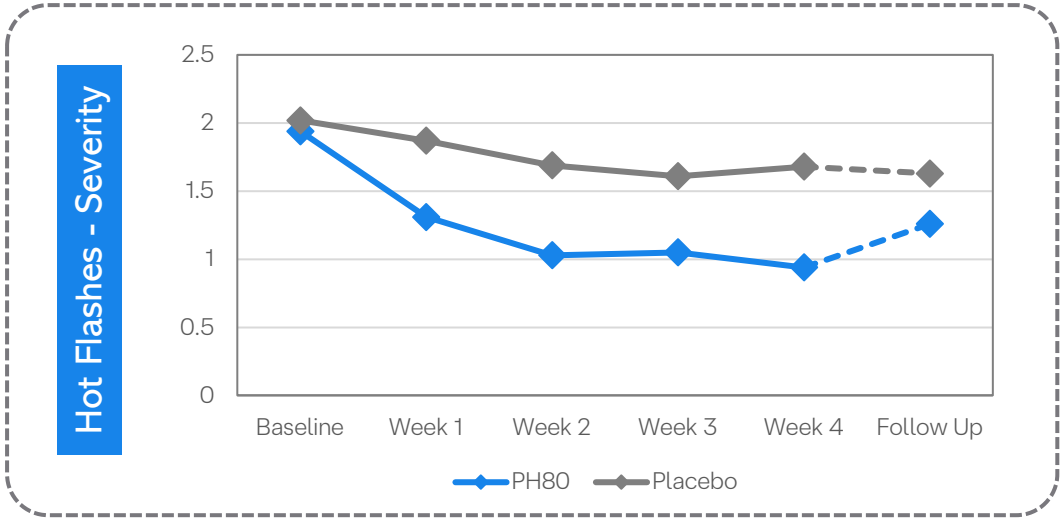
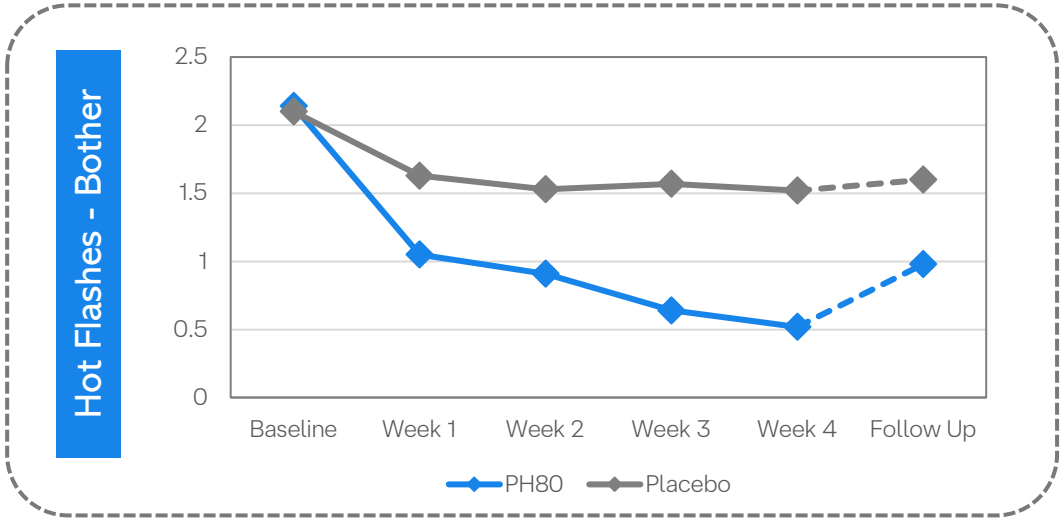
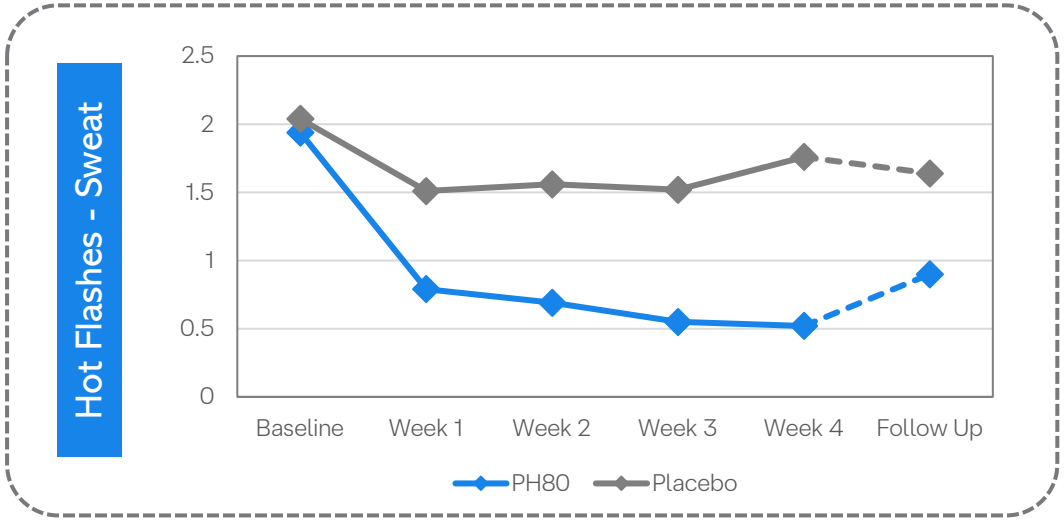
PH80 Phase 2A Study in Hot Flashes: Met Secondary Efficacy Endpoints

PH80 also significantly reduced participant-reported severity, disruption in function (Bother), and sweating associated with hot flashes during the treatment period as compared with placebo







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PH80 Phase 2A Study in Premenstrual Dysphoric Disorder (PMDD)

Objective: Proof-of-principle evaluation of PH80 efficacy and tolerability for the management of the symptoms of PMDD

Study Details: Randomized, double-blind, placebo-controlled, exploratory Phase 2A study. Subjects who did not respond to placebo at a screening visit returned after the onset of symptoms during the next menstrual cycle. At the second study visit, subjects were randomized to receive either 0.9 µg PH80 nasal spray or placebo, self-administered at home as-needed, up to 4 times per day for 6 consecutive days

Participants: Women aged 18-40 (n=52) with at least 1 year of experiencing PMDD symptoms and Premenstrual Tension Scale (PMTS) score ≥ 10. Individuals with relevant pre-existing conditions or use of SSRIs were excluded

Outcome Measures: Penn Daily Symptom Report (DSR), Premenstrual Tension Scale (PMTS), PGI-C, CGI-I, Safety, and Tolerability

Results: PH80 showed statistically and clinically significant improvement vs. placebo in symptoms of PMDD at study endpoint after 6 days of treatment (during the critical days of the menstrual period) based on DSR (p=0.008) and PMTS (p=0.006) and was well-tolerated with no serious adverse events

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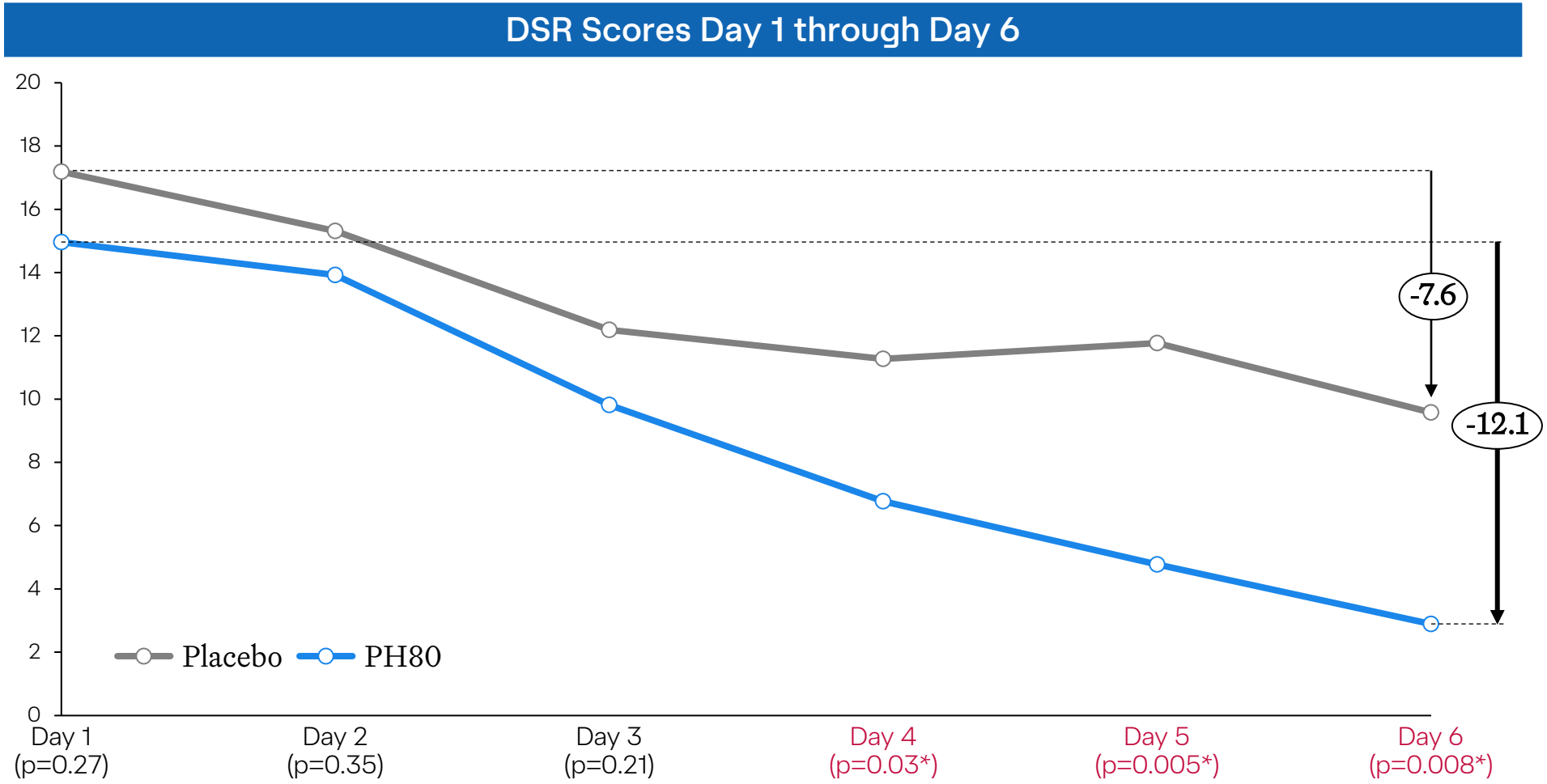
PH80 Phase 2A Study in PMDD: Met Primary Efficacy Endpoint

PH80 treatment resulted in significant separation in PMDD DSR scores vs placebo from Day 4 through Day 6 (p=0.008)



* Denotes Statistical Significance

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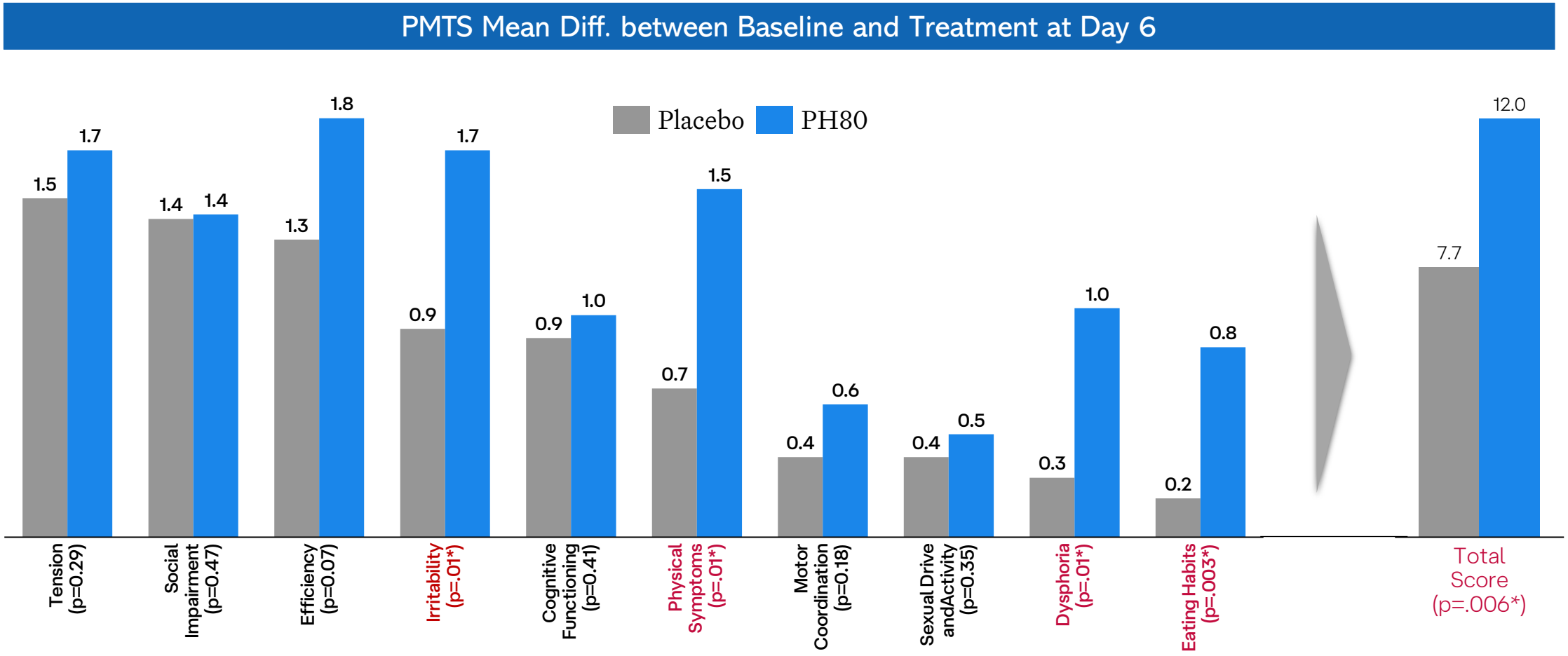
PH80 Phase 2A Study in PMDD: Met Primary Efficacy Endpoint

PH80 resulted in clinically significant reduction in PMTS from baseline vs Placebo (p=0.006)



* Denotes Statistical Significance

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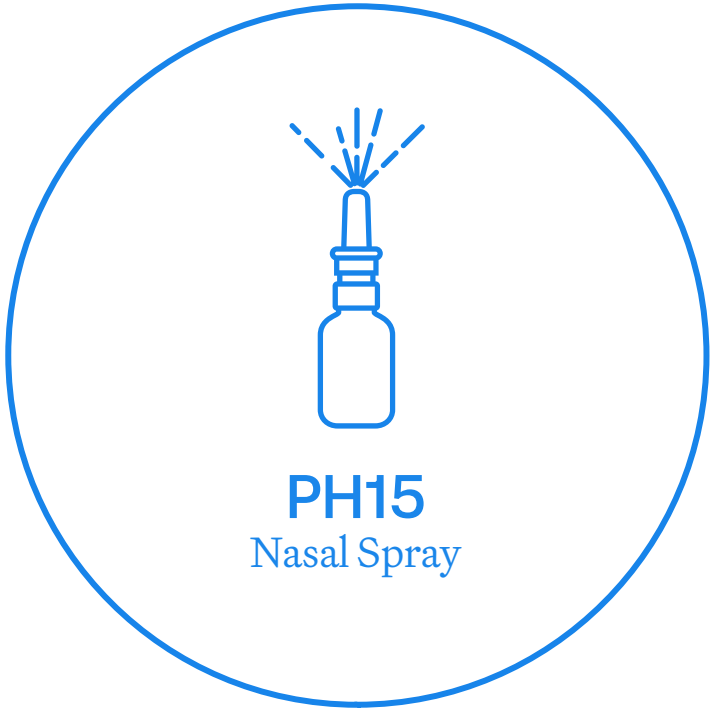
PH15 Nasal Spray for Acute Treatment of Cognitive Impairment caused by Mental Fatigue

Setting a new standard of care

PH15 Nasal Spray

Potential for improvement of cognitive impairment due to mental fatigue

- Novel and differentiated MOA provides potential new treatment for acute improvement of cognition and disorders that cause sleep deprivation and ensuing fatigue and cognitive impairment (e.g., Shift Work Disorder, Sleep Apnea, and Narcolepsy)
- Rapid-onset
- No systemic absorption
- No direct activity on neurons in the brain



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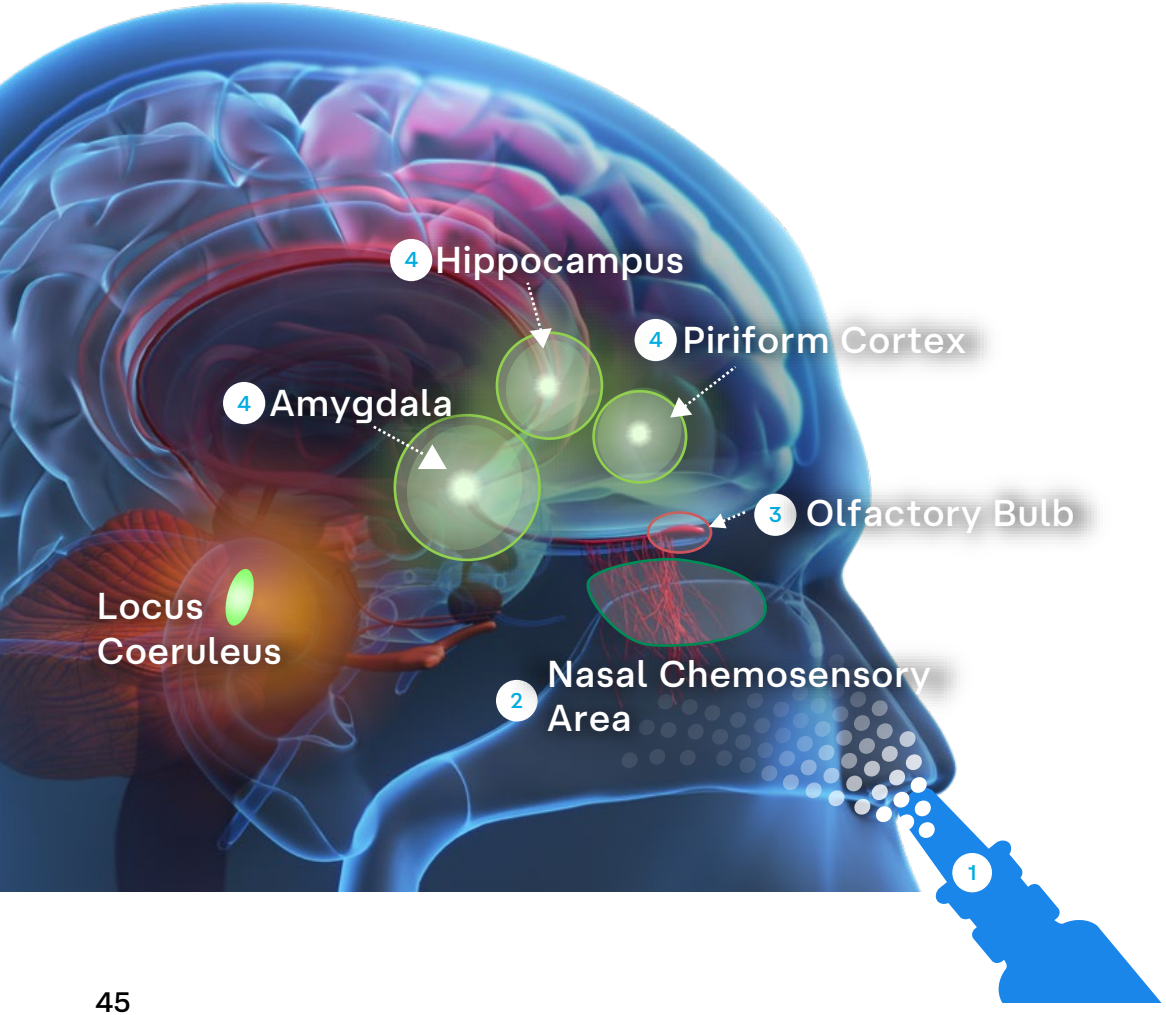
PH15 Novel Proposed Mechanism of Action

Differentiated from all currently approved therapies



1. Microgram-level intranasal dose of PH15 is administered intranasally
2. PH15 engages specific peripheral receptors in nasal chemosensory neurons (NCNs)
3. NCNs then trigger subgroups of neurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then directly stimulate neurons in several areas of the basal forebrain including the hippocampus, amygdala, and piriform cortex

Activity Increases

Increased activity in the hippocampus is responsible for improvement in cognitive function

Increased activity in the limbic amygdala in turn increases activity in the cerebral cortex, leading to improved psychomotor function

Sources: Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

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PH284 Nasal Spray for Acute Treatment of Wasting Syndrome (Cachexia)

Setting a new standard of care

PH284 Nasal Spray

Potential acute treatment for wasting syndrome (cachexia)

- Innovative, fast-acting therapy for appetite enhancement
- Intranasal administration, taken before meals
- Potential to increase subjective feelings of hunger and caloric intake in patients diagnosed with wasting syndrome, a severe consequence of many chronic diseases and advanced cancer
- Favorable tolerability and promising clinical activity
- Novel and differentiated MOA targets a neuronal circuit associated with appetite stimulation instead of a single gene, protein, neuron, or synapse, which may have therapeutic potential in wasting syndrome (cachexia)

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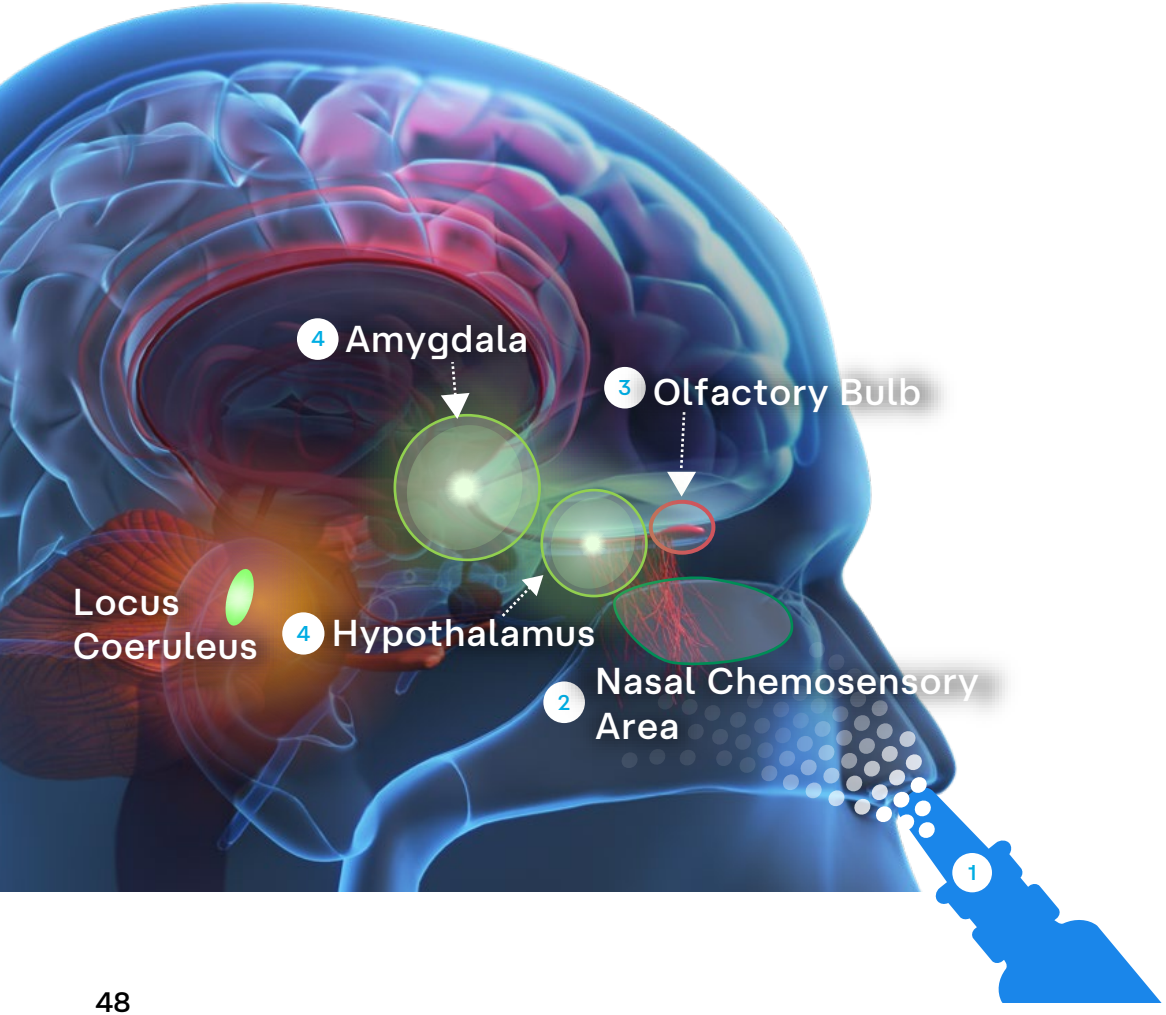
PH284 Novel Proposed Mechanism of Action

Differentiated from current treatment options



1. Microgram-level intranasal dose of PH284 is administered intranasally
2. PH284 engages specific peripheral receptors in nasal chemosensory neurons (NCNs)
3. Once stimulated with PH284, NCNs then trigger subsets of neurons in the olfactory bulbs (OBs)
4. Neurons in the OBs then stimulate neurons in the amygdala and the arcuate nucleus of the hypothalamus

Activity Increases

The stimulation of neurons in the arcuate nucleus of the hypothalamus increases activity of aguti-related peptide (AGRP) neurons and neuropeptide Y (NPY) neurons, which increase appetite and decrease energy expenditure

Both are key regulators of feeding, energy balance, and metabolic homeostasis

Sources: Monti L, and Liebowitz MR (2020). Neural circuits of anxiolytic and antidepressant pherine molecules. CNS Spectrums https://doi.org/10.1017/S109285292000190X

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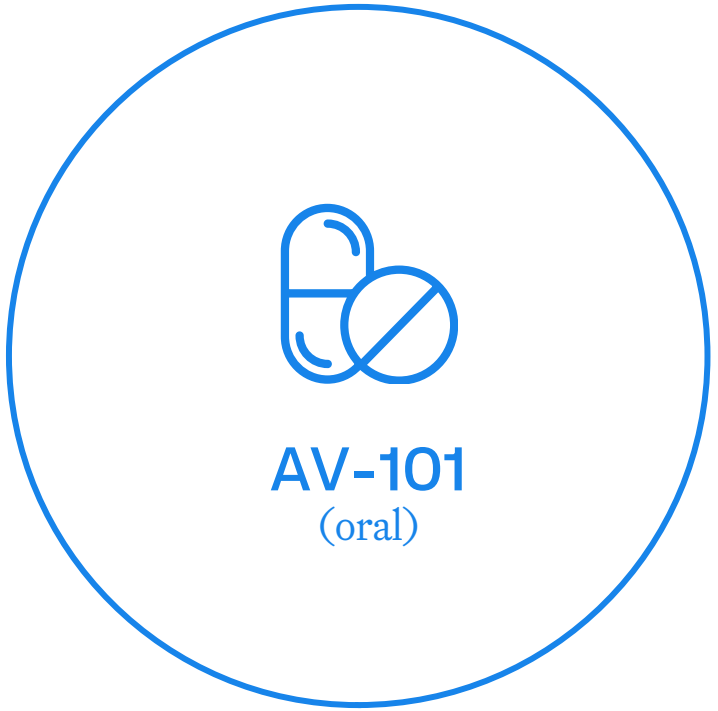
AV-101 for Potential Phase 2A Development

Setting a new standard of care for disorders involving the NMDA receptor

AV-101 for Multiple Disorders

Designed to inhibit (but not block) NMDA receptor activity

- Oral prodrug of 7-Cl-KYNA, a potent and selective full antagonist at the glycine site of the NMDA receptor
- Inhibition of the NMDA receptor, without fully blocking the receptor like ketamine and other NMDAR antagonists, is thought to reduce the side effect burden
- Well-tolerated in all clinical studies to date
- FDA Fast Track designations granted for adjunctive treatment of MDD and treatment of neuropathic pain
- Assessing go forward opportunities for collaborative Phase 2 development



Levodopa-Induced Dyskinesia
Associated with Parkinson's therapy

Seizures

Suicidal Ideation

Neuropathic Pain

Major Depressive Disorder

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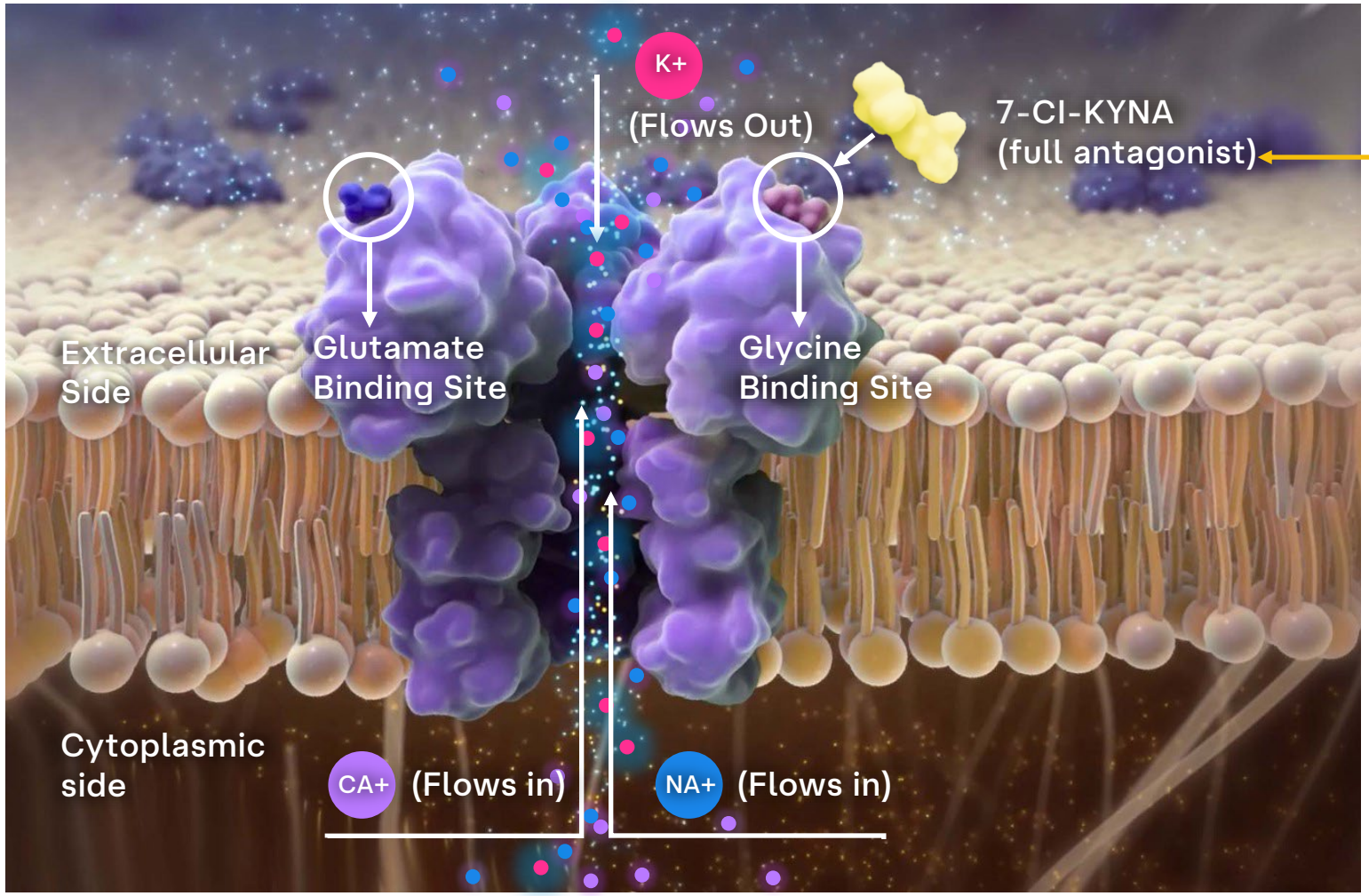
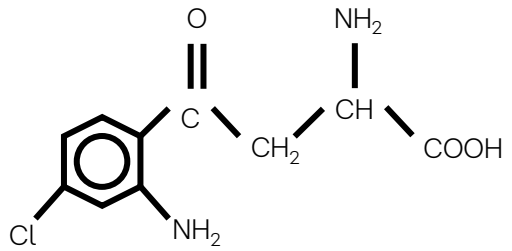
AV-101's Proposed Mechanism of Action

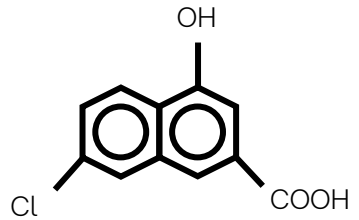


AV-101 - Oral Prodrug (4-Cl-KYN)



L-4-chlorokynurenine
(4-Cl-KYN) (oral delivery to CNS)

Activated  Astrocytes



AV-101 - Active Metabolite (7-Cl-KYNA)

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Distinguished Clinical and Regulatory Advisors

Representing premier institutions and deep neuroscience and regulatory expertise

Maurizio Fava, M.D.

Professor of Psychiatry, Harvard Medical School; Director, Division of Clinical Research, Massachusetts General Hospital (MGH) Research Institute; and Executive Vice Chair of the Department of Psychiatry

Thomas Laughren, M.D.

Director (retired), U.S. Food and Drug Administration (FDA) Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER)

Michael Liebowitz, M.D.

Former Columbia University psychiatrist, director and founder of the Anxiety Disorders Clinic at the New York State Psychiatric Institute; current Managing Director of The Medical Research Network LLC

Sanjay Mathew, M.D.

Vice Chair for Research and Professor of Psychiatry and Behavioral Sciences at Baylor College of Medicine; Staff Psychiatrist at the Michael E. DeBakey VA Medical Center

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